

Induction of labour

Clinical Guideline

July 2008

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Induction of labour

National Collaborating Centre for Women's
and Children's Health

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Health and Clinical Excellence

Evidence tables

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Evidence tables should be read in conjunction with the main guideline.

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Abbreviations

41 ⁺³ weeks	41 completed weeks plus 3 days of gestation, etc.
ARM	artificial rupture of the membranes
BNF	British National Formulary
CI	confidence interval
CS	caesarean section
EFM	electronic fetal monitoring
EL	evidence level (level of evidence)
FHR	fetal heart rate
GA	gestational age
GDG	Guideline Development Group
ICER	incremental cost-effectiveness ratio
IMN	isosorbide mononitrate
IUFD	intrauterine fetal death
IV	intravenous
LSCS	lower segment caesarean section
MAD	minimum analgesic dose
NCC-WCH	National Collaborating Centre for Women's and Children's Health
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
NICU	neonatal intensive care unit
NNT	number needed to treat
NS	not significant
OR	odds ratio
PCT	primary care trust
PG	prostaglandin
PGE ₂	prostaglandin E ₂
PGF _{2α}	prostaglandin F ₂ alpha
PPIP	Patient and Public Involvement Programme
QALY	quality-adjusted life year
RCOG	Royal College of Obstetricians and Gynecologists
RCT	randomised controlled trial
RR	relative risk
SD	standard deviation
SIGN	Scottish Intercollegiate Guidelines Network
SPC	summary of product characteristics
VE	vaginal examination
WHO	World Health Organization
WMD	weighted mean difference

3 Information and decision making

Bibliographic details	Study type and evidence level	Aim of study	Number of patients and patient characteristics	Population characteristics	Outcome measures	Reviewer comments
Shetty (2005) ¹⁶ Country: UK	Study Type: Cohort Evidence Level: 2+	To assess women's actual experience of the process of induced labour and their satisfaction with labour.	Total number of patients = 699 Women who laboured spontaneously <i>n</i> = 385 Women undergoing induction of labour at term (with vaginal PGE ₂) <i>n</i> = 31	Women undergoing induction of labour at term and those labouring spontaneously.	Satisfaction with labour: 70% versus 80%, RR 0.89 (95% CI 0.8 to 0.96) Perception of pain of labour: more painful 50% versus 56% (NS) Complications with labour: more expected 37% versus 37% (NS) Perception of length of labour: longer 33% versus 29% (NS) Satisfaction with information received about induction prior to induction: NA Aspects women liked to see changed if women were to have another induction All women: 65% Liked to change speed of induction: 40% Fewer vaginal exam: 7% fewer complications: 9%	Funding: Not stated Questionnaire survey, likelihood of bias
Jacoby (1987) ¹⁵ Country: UK	Study Type: Other Evidence Level: 3	To assess women's preferences for and satisfaction with procedures in childbirth.	Total number of women = 1920	Women who had recently given birth.	Women's preferences over obstetric procedures (preferred not to/hoped it would not be necessary Induction by drug: 83% Membranes ruptured: 72% Epidural: 72% Women achieving their wishes (those who had wanted it) Induction by drug: 59% Membranes ruptured: 78% Epidural: 66% Women achieving their wishes (those who had not wanted it) Induction by drug: 23% Membranes ruptured: 59% Epidural: 11% Women's preferences over the social aspects (wanted the following)	Source of Funding: MRC Response rate 75% Retrospective: likelihood of bias in recall subjective data non-comparative result may not be generalisable

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Bibliographic details	Study type and evidence level	Aim of study	Number of patients and patient characteristics	Population characteristics	Outcome measures	Reviewer comments
					<p>Move freely in first stage of labour: 73%</p> <p>Father present all/some of labour: 90%</p> <p>Father present at delivery: 88%</p> <p>Hold baby as soon as born: 93%</p> <p>Labour/delivery managed as liked</p> <p>Able to move freely: 69% (yes); 45% (no)</p> <p>Baby's father present: 65% (all labour), 49% (part), 51% (not at all)</p> <p>Baby's father present : 64% (at birth), 47% (not at birth)</p> <p>Able to hold baby: 65% (yes), 35% (no)</p> <p>Procedures managed as liked (those who wanted the procedure)</p> <p>Induction by drugs: 59% had it, 62% didn't have it</p> <p>Epidural: 54% had it, 59% didn't have it</p> <p>Overall: 18% women whose labours were managed as they liked reported feeling depressed postnatally, 25% of those whose labours were managed as they liked in some ways but not in others, and 30% of those whose labours were not managed as they liked, did so.</p>	
Cartwright (1977) ¹⁴	Study Type: Other	To assess women's experiences of pregnancy, labour and birth.	Total number of patients = 524	Women who had undergone induction of labour and had a live birth.	<p>No clear association between induction and the mother's age and parity</p> <p>Despite being given more pain relief, those induced reported similar intensities of pain during the 1st and 2nd stages of labour to those whose labour started spontaneously.</p> <p>The period they had contractions was shorter for the induced than for those starting spontaneously, and the intensity of pain at delivery was rated somewhat less by those who were induced.</p> <p>Two-fifth of mothers who were induced would have liked more information about induction</p> <p>Two-fifth of mothers said they had not discussed induction with a doctor, midwife or nurse during pregnancy</p> <p>17% of mothers who had induction said they would prefer to be induced again, 63% of those who had epidural would opt for the same procedures next time</p>	<p>Source of Funding: DHSS</p> <p>Retrospective: recall bias non-comparative, non-interventional, subjective data may not be generalisable, study published in 1977.</p>

Bibliographic details	Study type and evidence level	Aim of study	Number of patients and patient characteristics	Population characteristics	Outcome measures	Reviewer comments
Stewart (1977) ¹³ Country: UK	Study Type: Other Evidence Level: 3	To assess women's' attitudes towards planned induction of labour (amniotomy with oxytocin or oxytocin with delayed amniotomy).	Total number of patients = 137	Women due for induction of labour (24 hours before and 12 hours after delivery).	<p>Source of information on induction before this pregnancy</p> <p>Relatives and friends: 37%</p> <p>Newspaper/TV: 14%</p> <p>Hospital: 5%</p> <p>Cannot remember: 1%</p> <p>Never heard of induction: 22%</p> <p>From previous induction: 25%</p> <p>Opinions on induction before this pregnancy:</p> <p>Would prefer natural labour: 19%</p> <p>Adverse opinions: 1.5%</p> <p>In favour of induction: 2%</p> <p>Accept induction for sake of baby: 13%</p> <p>Thought induction was carried out for the convenience of the hospital: 0.7%</p> <p>Frightened: 0.7%</p> <p>Non-committal: 14%</p> <p>Never heard of induction: 22%</p> <p>Women's attitude towards own induction</p> <p>Glad: 66%</p> <p>Accept for baby's sake: 6%</p> <p>Relieved to know outcome: 0.7%</p> <p>Indifferent: 16%</p> <p>Reluctant: 11%</p> <p>Women's description of methods of induction</p> <p>Painful: amniotomy (15%), IV infusion (10%)</p> <p>Uncomfortable: amniotomy (53%), IV infusion (54%)</p> <p>Frightening: amniotomy (5%), IV infusion (2%)</p> <p>Indifferent: amniotomy (28%), IV infusion (35%)</p>	<p>Source of Funding: Not stated</p> <p>Comments: non comparative subjective data likelihood of bias may not be generalisable study published 1977</p>

4 Induction of labour in specific circumstances

4.1 Prolonged pregnancy

Bibliographic details	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
Hilder (1998) ²¹ Country: UK	Study Type: Observational retrospective analysis Evidence Level: 3	171 527 births	Notified births in NE Thames Region, London 1989 - 1991	Stillbirth and infant mortality rates at term and post-term gestation.	<p>Stillbirth/1000 ongoing pregnancies</p> <p>37 weeks GA 0.35 (95% CI 0.26 to 0.44)</p> <p>38 weeks GA 0.56 (95% CI 0.44 to 0.68)</p> <p>39 weeks GA 0.57 (95% CI 0.44 to 0.70)</p> <p>40 weeks GA 0.86 (95% CI 0.68 to 1.05)</p> <p>41 weeks GA 1.27(95% CI 0.92 to 1.62)</p> <p>42 weeks GA 1.55 (95% CI 0.79 to 2.31)</p> <p>≥ 43 weeks GA 2.12 (95% CI 0.55 to 5.43)</p> <p>Neonatal and post neonatal mortality/1000ongoing pregnancies</p> <p>37 weeks GA 0.34 (95% CI 0.25 to 0.43)</p> <p>38 weeks GA 0.70 (95% CI 0.56 to 0.83)</p> <p>39 weeks GA 0.83 (95% CI 0.68 to 0.99)</p> <p>40 weeks GA 1.57 (95% CI 1.31 to 1.82)</p> <p>41 weeks GA</p>	Induced labours included, number unknown

Bibliographic details	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
					1.48 (95% CI 1.10 to 1.85) 42 weeks GA 3.29 (95% CI 2.19 to 4.40) ≥ 43 weeks GA 3.71 (95% CI 1.53 to 7.63)	
					Total pregnancy loss rate/1000 ongoing pregnancies	
					37 weeks GA: 0.7 38 weeks GA: 1.3 39 weeks GA: 1.4 40 weeks GA: 2.4 41 weeks GA: 2.8 42 weeks GA: 4.8 ≥ 43 weeks GA: 5.8	
Olesen (2003) ²⁷	Study Type: Cross-sectional	Post-term delivery (n = 77 956)	Registry data 1978–1993	Post-term delivery versus term delivery	<u>Perinatal outcomes</u> Aspiration: 1.3% versus 0.7%, Adjusted OR 1.75 (95% CI 1.52 to 2.02) Asphyxia before delivery: 0.8% versus 0.4%, Adjusted OR 1.90 (95% CI 1.58 to 2.30) Asphyxia during delivery: 0.2% versus 0.1%, Adjusted OR 2.00 (95% CI 1.33 to 3.01) Asphyxia in perinatal period: 1.5% versus 0.9%, Adjusted OR 1.63 (95% CI 1.43 to 1.85) Asphyxia in neonatal period: 2.4% versus 1.6%, Adjusted OR 1.33 (95% CI 1.62 to 1.85) Apgar score at 5 minutes < 7: 0.95 versus 0.6%, Adjusted OR 1.44 (95% CI 1.23 to 1.69) Pneumonia: 0.2% versus 0.2%, Adjusted OR 1.47 (95% CI 1.07 to 2.01) Septicaemia: 0.5% versus 0.4%, Adjusted OR 1.37 (95% CI 1.12 to 1.67) Stillbirth: 0.2% versus 0.2%, Adjusted OR 1.24 (95% CI 0.93 to 1.66) Death day 1–7: 0.1% versus 0.1%, Adjusted OR 1.60 (95% CI 1.07 to 2.37) Perinatal death: 0.4% versus 0.3%, Adjusted OR 1.36 (95% CI 1.08 to 1.72)	Not clear if women were low-risk
Country: Denmark	Evidence Level: 3	Gestational age: 42 weeks (87.5%) 43 weeks (11.6%) 44 weeks (0.8%) 45+ weeks (0.1%)	All singleton deliveries			Induced labours excluded
		Induced delivery after 42 weeks: 24.5%				Post-term pregnancy: ≥ 42 weeks
		Term delivery (n = 34 140) Gestational age: 37–39 weeks (34.5%) 40–41 weeks (65.5%)				
					<u>Maternal complications</u> Puerperal infection: 0.8% versus 0.7%, Adjusted OR 1.21 (95% CI 1.03 to	

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Bibliographic details	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
					<p>1.41)</p> <p>Post-partum haem: 5.0% versus 3.6%, Adjusted OR 1.37 (95% CI 1.28 to 1.46)</p> <p>Large fetus: 0.6% versus 0.2%, Adjusted OR 3.58 (95% CI 2.72 to 4.70)</p> <p>Cephalopelvic disproportion: 4.6% versus 2.4%, Adjusted OR 1.91 (95% CI 1.77 to 2.07)</p> <p>Vulval incomplete rupture: 5.5% versus 5.8%, Adjusted OR 0.96 (95% CI 0.91 to 1.02)</p> <p>Vulval complete rupture: 0.7% versus 0.6%, Adjusted OR 1.11 (95% CI 0.95 to 1.30)</p> <p>Cervical rupture: 1.1% 0.7%, Adjusted OR 1.45 (95% CI 1.26 to 1.67)</p> <p>Delivery with threatening asphyxia: 8.0% versus 3.9%, Adjusted OR 2.03 (95% CI 1.91 to 2.16)</p> <p>Dystocia: 0.3% versus 0.2%, Adjusted OR 1.71 (95% CI 1.30 to 2.25)</p> <p>Acute CS: 12.8% versus 8.2%, Adjusted OR 1.58 (95% CI 1.51 to 1.66)</p>	
Smith (2001) ²⁶	Study Type: Case -series Evidence Level=3	Birth data (n = 700 878)	National database in Scotland 1985–1996 All deliveries singletons	Perinatal death at term and postterm.	<p>Cumulative probability of antepartum stillbirth (per 1000 ongoing pregnancy)</p> <p>At 37 weeks: 0.4</p> <p>At 38 weeks: 0.8</p> <p>At 39 weeks: 1.3</p> <p>At 40 weeks: 2.2</p> <p>At 41 weeks: 3.4</p> <p>At 42 weeks: 5.3</p> <p>At 43 weeks: 11.5</p> <p>Probability of intrapartum stillbirth (per 1000 live birth):</p> <p>At 37 weeks: 0.7</p> <p>At 38 weeks: 0.3</p> <p>At 39 weeks: 0.2</p> <p>At 40 weeks: 0/3</p> <p>At 41 weeks: 0.3</p> <p>At 42 weeks: 0.4</p> <p>At 43 weeks: 0</p>	<p>Excluded: multiple pregnancies and deaths caused by congenital abnormalities</p> <p>Induced labours included, number unknown</p> <p>Funding: Wellcome Trust</p>
Heimstad (2006) ²⁸	Study type: Prospective study Evidence level = 3	Pregnancies (n = 27 514, labour induced in 2500) Para 0: 43%	Gestations beyond 37 weeks, all singleton deliveries.	Pregnancy outcomes by weeks of gestation	<p><u>Maternal complications:</u> <u>Induced versus spontaneous labour</u></p> <p>Caesarean delivery</p> <p>At 37 weeks: OR 1.2 (95% CI 0.8 to 1.8)</p>	<p>Not clear if women were low-risk</p> <p>Induced labours: 9%</p>

Bibliographic details	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
		Para 1: 38% Para 2: 20%			<p>At 38 weeks: OR 2.5 (95% CI 1.8 to 3.4) At 39 weeks: OR 3.8 (95% CI 2.7 to 5.2) At 40 weeks: OR 3.8 (95% CI 2.8 to 5.0) At 41 weeks: OR 4.0 (95% CI 3.0 to 5.4) At 42 weeks: OR 2.8 (95% CI 2.2 to 3.7)</p> <p>Operational vaginal delivery At 37 weeks: OR 2.0 (95% CI 1.2 to 3.2) At 38 weeks: OR 2.2 (95% CI 1.5 to 3.0) At 39 weeks: OR 1.7 (95% CI 1.2 to 2.3) At 40 weeks: OR 1.6 (95% CI 1.2 to 2.1) At 41 weeks: OR 2.0 (95% CI 1.6 to 2.7) At 42 weeks: OR 1.0 (95% CI 0.8 to 1.3)</p> <p>Maternal haemorrhage At 37 weeks: OR 1.9 (95% CI 1.2 to 2.9) At 38 weeks: OR 1.8 (95% CI 1.3 to 2.7) At 39 weeks: OR 1.9 (95% CI 1.3 to 2.7) At 40 weeks: OR 2.2 (95% CI 1.7 to 2.8) At 41 weeks: OR 2.3 (95% CI 1.7 to 3.1) At 42 weeks: OR 1.5 (95% CI 1.1 to 2.0)</p> <p>Fetal complications Meconium aspiration (per 1000 births) At 37 weeks: 2.5 At 38 weeks: 2.3 At 39 weeks: 1.8 At 40 weeks: 2.9 At 41 weeks: 5.1 At 42 weeks: 4.7</p> <p>Intrauterine fetal death (per 1000 ongoing pregnancies) At 37 weeks: 0.35 At 38 weeks: 0.25 At 39 weeks: 0.43 At 40 weeks: 0.51 At 41 weeks: 0.84 At 42 weeks: 1.55</p>	Funding: not stated

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Bibliographic details	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
					Risk factors for delivery complications by logistic regression analysis: Induction of labour: OR 1.3 to 2.8, independent of gestational age	
Caughey (2006) ²⁹	Study type: Retrospective cohort	Pregnant women (n = 32 828)	Low-risk women 37 to 40 weeks of gestation, all singleton deliveries.	Mode of delivery.	Mode of delivery	Funding: NICHD
Country: US	Evidence level: 3	Nulliparous: 52.1%		Maternal complications by weeks of gestation.	Primary caesarean (%) At 37 weeks: 9.7 At 38 weeks: 8.7 At 39 weeks: 9.2 At 40 weeks: 10.4** At 41 weeks: 14.1** At 42 weeks: 18.1***	Induced labours:12%
		Labour induced: 12.2%				
		Birthweight ≥ 4000 g: 12.6%				
		Sugmentation of labour: 25.7%			Operative vaginal delivery (%) At 37 weeks: 14.9 At 38 weeks: 14.0 At 39 weeks: 14.8* At 40 weeks: 16.4** At 41 weeks: 17.4** At 42 weeks: 20.2***	
		Caesarean delivery: 17.6%				
		Primary caesarean rate: 11.7%				
		Operative vaginal delivery: 15%			Mode of delivery Primary caesarean (%) At 37 weeks: 10.9 At 38 weeks: 10.2 At 39 weeks: 11.4 At 40 weeks: 14.2** At 41 weeks: 18.9*** At 42 weeks: 25.9***	
					Operative vaginal delivery (%) At 37 weeks: 22.0 At 38 weeks: 20.7 At 39 weeks: 21.9 At 40 weeks: 23.1* At 41 weeks: 23.0 At 42 weeks: 26.4***	

Bibliographic details	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
					<p>Maternal complications by weeks of gestation</p> <p>Postpartum haem</p> <p>At 37 weeks: 14.2</p> <p>At 38 weeks: 12.6</p> <p>At 39 weeks: 13.4</p> <p>At 40 weeks: 12.8</p> <p>At 41 weeks: 16.0***</p> <p>At 42 weeks: 15.8</p> <p>* < 0.05, ** < 0.01, *** < 0.001</p> <p>(Statistical significant as compared with the rate in the prior week of gestation)</p>	
Gulmezoglu (2006) ³¹	Study type: systematic review Evidence level: 1++	19 RCTs (7984 women)	<p>Trials conducted between 1969 to 2005</p> <p>Participants were low-risk women with certain gestational age</p> <p>Induction at 38–40 weeks (3 trials)</p> <p>Induction at 41 completed weeks (11 trials)</p> <p>Induction after 42 completed weeks (5 trials)</p>	<p>Planned induction of labour (All methods, singly or in combination: membrane sweeping, AROM, laminaria tents, prostaglandins, misoprostal, oxytocin)</p> <p>versus</p> <p>No induction (Expectant management: monitoring with fetal movements, nonstress tests, amniotic fluid measurement and ultrasound etc).</p>	<p><u>Perinatal death</u></p> <p>Induction at 41 completed weeks (10 RCTs): (0/2835 versus 6/2808, RR 0.25 (95% CI 0.05 to 1.18)</p> <p>Induction at 41 and 42 completed weeks (12 RCTs): RR 0.30 (95% CI 0.09 to 0.99)</p> <p>Excluding death due to congenital anomalies: 0 versus 9</p> <p><u>Birth asphyxia</u></p> <p>Induction at 38–40 weeks (1RCT): (29/481 versus 7/235; RR 2.02 (95% CI 0.90 to 4.55)</p> <p>Induction at 41 completed weeks (1RCT): (1/124 versus 0/125)</p> <p><u>Meconium aspiration syndrome</u></p> <p>Induction at 41 completed weeks (4 RCTs): RR 0.29 (95% CI 0.12 to 0.68)</p> <p>Induction after 42 completed weeks (2 RCTs): RR 0.66 (95% CI 0.24 to 1.81)</p> <p><u>Mean birthweight (g):</u></p> <p>Induction at 41 completed weeks</p> <p>Similar between groups</p> <p>Induction after 42 completed weeks (3 RCTs):</p> <p>WMD -101.67 (95% CI -179.12 to -24.23)</p> <p><u>Caesarean section</u></p> <p>Induction at 38–40 weeks: RR 0.58 (95% CI 0.34 to 0.99)</p>	<p>Gestational age not confirmed by ultrasound in some trials.</p> <p>9 trials conducted after 1990</p> <p>4 trials conducted in developing countries</p> <p>Funding: WHO, University of Adelaide</p>

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Bibliographic details	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
					<p>Induction at 41 completed weeks: RR 0.92 (95% CI 0.76 to 1.12) Induction after 42 completed weeks: RR 0.97 (95% CI 0.72 to 1.31)</p> <p><u>Assisted vaginal birth</u> Induction at 38–40 weeks: RR 1.71 (95% CI 1.23 to 2.39) Induction at 41 completed weeks: RR 1.05 (95% CI 0.94 to 1.17) Induction after 42 completed weeks: RR 0.95 (95% CI 0.65 to 1.38)</p> <p><u>Cervical status (8 trials):</u> No significant difference between induction and expectant management for CS or assisted vaginal birth</p> <p><u>Maternal anxiety/satisfaction:</u> Not reported in any of the trials</p>	
Hannah (1992) ³³ Country: Canada	Study type: Randomised Controlled Trial Evidence level: 1+	Total number of patients = 3407 Induction of labour with intracervical PGE ₂ gel <i>n</i> = 1701 Serial monitoring <i>n</i> = 1706	Uncomplicated pregnancies ≥ 41 weeks GA Nulliparity Induction: 68% monitoring: 68% Cervical dilation before entry 0 cm Induction: 40% monitoring: 40% 1–2 cm Induction: 51% monitoring: 49% 3–4 cm Induction: 1% monitoring: 1%	Induction of labour (PGE ₂ gel) versus Serial monitoring	Caesarean section rate: 21.2% versus 24.5% (<i>P</i> = 0.003) instrumental vaginal birth rate: 35.3% versus 34.9% (NS) intrapartum fever > 38 °C: 2.9% versus 3.6% (NS) Apgar score < 7 at 5 minutes: 1.1% versus 1.2% (NS) Seizures: 0.2% versus 0.3% (NS) Admission to NICU: 14.1% versus 15.5% (NS) Stillbirth: 0 versus 2 Neonatal death; 0 versus 0	Source of Funding: MRC, Canada Central randomisation. Unclear method of allocation concealment Power calculation Serial monitoring: underwent non-stress tests 3 times/week, ultrasound assessment of amniotic fluid volume 2–3 times/week Women asked to count no. of times they felt fetus kick over a 2 hour period each day (kick counts), and to contact their physicians if they counted < 6 kicks in 2 hours and to have a non-stress test within 12 hours 7 women whose infants had major congenital anomalies were excluded from the

Bibliographic details	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
McNellis (1994) ³² Country: USA	Study type: Randomised controlled trial Evidence level: 1+	Total number of patients = 265 Intracervical PGE ₂ gel n = 174 Placebo n = 91	Uncomplicated pregnancies 41–43 weeks GA (verified by US) Nulliparity PGE ₂ : 60% Placebo: 59% Mean Bishop score PGE ₂ : 4 (SD 1.4) Placebo: 3.8 (SD 1.4)	Induction of labour (Intracervical PGE ₂ gel) versus No induction (placebo)	Randomisation-to-delivery interval (hours): 36 (6–492) versus 35 (7–387) (NS) Maternal infection: 19% versus 14% (NS) Maternal need for transfusion: 1% versus 0% (NS) Uterine hyperactivity: 1% versus 1% (NS) Vaginal delivery: 77% versus 82% (NS) CS: 22% versus 18% (NS) Apgar score < 4 at 5 minutes (No): 0 versus 0 (NS) No meconium (No.): 131 (75%) versus 71 (78%) (NS) Thin meconium (No.): 31 (18%) versus 12 (13%) (NS) Thick meconium (No.): 10 (6%) versus 7 (8%) (NS) Meconium aspirated pneumonia (No.): 1 versus 1 (NS)	analysis of perinatal and neonatal outcomes Source of Funding: NICHHD, US Part of a RCT to assess effects of induction of labour versus expectant management. Women in the induction group underwent induction within 24 hours of randomisation to PGE ₂ gel or placebo prior to induction with oxytocin Power calculation Computer randomisation in a 2:1 scheme (PGE ₂ :placebo)
Balchin (2007) ³⁰ Country: UK	Prospective cohort study of maternity records Evidence level: 2+	Total number of women = 197 061 in 15 maternity units	81% white, 13% South Asian, 6% black women who delivered a single baby weighing ≥ 500 g at 24–43 weeks	Compare perinatal mortality (PNM) according to length of gestation in white, south Asian and black women	<u>Crude PNM rates/1000births</u> White women vs South Asian women: 5.6 vs 9.2 (OR 1.6, 95% CI 1.4 to 1.9) White women vs black women: 5.6 vs 10.8 (OR 2.0, 95% CI 1.6 to 2.3) <u>Crude stillbirth rates/1000births</u> White women vs South Asian women: 4.3 vs 7.5 (OR 1.8, 95% CI 1.5 to 2.1) White women vs black women: 4.3 vs 7.8 (OR 1.8, 95% CI 1.5 to 2.3) <u>Crude antepartum stillbirth rates/1000births</u> White women vs South Asian women: 3.3 vs 6.2 (OR 1.9, 95% CI 1.6 to 2.2) White women vs black women: 3.3 vs 6.3 (OR 1.9, 95% CI 1.5 to 2.4) <u>Crude intrapartum stillbirth rates/1000births</u> White women vs South Asian women: 0.6 vs 0.5 (OR 0.9, 95% CI 0.5 to 1.5) White women vs black women: 0.6 vs 1.2 (OR 2.0, 95% CI 1.1 to 3.4)	none

Induction of labour

Bibliographic details	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
					<p><u>Crude early neonatal death rates/1000births</u></p> <p>White women vs South Asian women: 1.3 vs 1.8 (OR 1.3, 95% CI 1.0 to 1.8)</p> <p>White women vs black women: 1.3 vs 3.1 (OR 2.3, 95% CI 1.6 to 3.3)</p> <p>Independent factors associated with antepartum stillbirth (corrected for confounding variables [placental abruption, congenital abnormality, low birthweight, birthweight < 10th centile, meconium opassage, fever, maternal BMI ≥ 30, maternal age ≥ 30])</p> <p>South Asian: OR 1.8, 95% CI 1.2 to 2.7</p>	

4.2 Preterm prelabour rupture of membranes

Bibliographic details	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
Naef (1998) ⁴⁴ Country: US	Study Type: Randomised Controlled Trial Evidence level: 1++	Total number of patients = 120 Induction with IV oxytocin <i>n</i> = 57 conservative management by observation <i>n</i> = 63	Women with preterm prelabour rupture of membranes between 34 and 37 weeks of gestation (mixed parity).	Induction with IV oxytocin versus conservative management by observation	Admission-to-delivery interval (hours): 9.8 (7.8) versus 119 (223) (<i>P</i> = 0.001) Chorioamnionitis: 2% versus 16% (<i>P</i> = 0.007) Hospital stay (days): 2.6 (1.6) versus 5.2 (6.8) (<i>P</i> = 0.006) CS: 7% versus 5% (NS) Apgar score at 5 minutes: 9.1 (0.9) versus 9.1 (0.7) (NS) NICU admission: 19% versus 24% (NS) Sepsis: 0% versus 5% (NS) Total hospital stay (days): 4.5 (4.9) versus 4.8 (5.1) (NS)	Source of Funding: not stated computer-generated randomisation, allocation in sealed opaque envelopes Power calculation All women received antibiotic prophylaxis No tocolytics or corticosteroids given
Haghighi (2006) ⁴⁶ Country: Iran	Study Type: Randomised controlled trial Evidence level: 1+	Total number of patients = 108 Vaginal misoprostol 25 mg <i>n</i> = 54 IV oxytocin <i>n</i> = 54	Women with preterm prelabour rupture of membranes and unfavourable cervix at 29 to 36 weeks of gestation.	Vaginal misoprostol 25 mg versus IV oxytocin.	Admission to delivery interval (minutes, mean): 507.68 (248.0) versus 596.66 (246.38) (<i>P</i> < 0.005) CS due to failed induction: 9% versus 19% (<i>P</i> < 0.004) Vaginal birth: 83% versus 76% (NS) Apgar score < 7 at 5 minutes (no) : 1 versus 1 (NS)	Source of Funding: not stated Sequential sealed envelopes numbered by means of random number tables No power calculation All women received antibiotics and dexamethasone if gestation < 34 weeks
Cox (1995) ⁴³ Country: US	Study Type: Randomised controlled trial Evidence Level: 1+	Total number of patients = 129 Intentional delivery (oxytocin or caesarean birth) <i>n</i> = 61 Expectant management <i>n</i> = 68	Women with preterm prelabour rupture of membranes at 30 to 34 weeks of gestation.	Intentional delivery (oxytocin or caesarean birth) versus expectant management	Admission to delivery intervals < 24 hours: 97% versus 25% (<i>P</i> < 0.001) CS: 23% versus 12% (NS) Chorioamnionitis: 2% versus 15% (<i>P</i> = 0.009) Stillbirth: 0% versus 1.4% (NS) (1 death from <i>E. coli</i> sepsis) Neonatal death: 5% (3 deaths: 1 from group B streptococcal sepsis, 1 from staphylococcus aureus and 1 from pulmonary hypoplasia) versus 0 (NS) Special care nursery stay: 19.9 days versus 19.3 days (NS)	Source of Funding: not stated Randomisation using random number tables allocation predetermined and placed in consecutively numbered sealed envelopes. No power calculation. No tocolytics, corticosteroids or prophylactic antibiotics were used during the trial.
	Study Type: Randomised controlled trial	Total number of patients = 109	Women with preterm prelabour rupture of membranes =	Vaginal misoprostol 50 µg versus	Insertion to delivery (hr, mean): 16.4 ± 10.2 versus 22.0 +/- 12.9 (<i>P</i> = 0.01)	Source of Funding: not stated

Induction of labour

Bibliographic details	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
	Evidence level: 1+	Vaginal misoprostol 50 µg <i>n</i> = 54	34 weeks of gestation (median 36 weeks).	vaginal PGE ₂ 2.5 mg.	Delivery within 12 hours: 41% versus 16% (<i>P</i> = 0.005) Tachysystole: 20% versus 6% (<i>P</i> = 0.02) Uterine hyperstimulation: 9% versus 0% (<i>P</i> = 0.02) CS: 19% versus 26% (NS)	Computer-generated randomisation, allocations placed in consecutively numbered sealed opaque envelopes, power calculation.
		vag PGE ₂ 2.5 mg <i>n</i> = 55				
Mercer (1993) ⁴²	Study Type: Randomised controlled trial	Total number of patients = 93	Women with preterm prelabour rupture of membranes at 32 to 36 weeks of gestation.	Induction of labour versus expectant management.	Latency from randomisation to delivery (hr, median): 14 versus 36 (<i>P</i> < 0.001) Maternal hospitalisation (days, median): 2.3 versus 3.5 (<i>P</i> < 0.001) Overall chorioamnionitis: 11% versus 28% (<i>P</i> = 0.06) CS: 9% versus 6% (NS) Apgar score < 7 at 5 minutes: 0% versus 0% (NS) Neonatal hospital stay (days, median): 6.2 versus 7.3 (<i>P</i> = 0.09) Suspected neonatal sepsis: 28% versus 60% (<i>P</i> = 0.003) Antimicrobial therapy (neonates): 35% versus 79% (<i>P</i> = 0.001)	Source of Funding: not stated
Country: US	Evidence level: 1+	Induction of labour <i>n</i> = 46				Computer-generated randomisation Methods of allocation concealment not reported No power calculation
		Expectant management (Expectant management included hospitalisation, assessment of fetal heart rate, chorioamnionitis and labour. Digital cervical examinations were prohibited until progress labour occurred) <i>n</i> = 47				

4.4 Previous caesarean birth

Bibliographic details	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
Vause (1999) ⁶⁸ Country: UK, US, Sweden, Israel	Study Type: Systematic review/ meta-analysis Evidence level: 1+	1 RCT (42 women) 6 Observational studies (724 women)	Women with a caesarean birth scar undergoing induction of labour.	Vaginal PGE ₂ 2.5 mg followed by amniotomy versus amniotomy + IV oxytocin (1 RCT) 6 observational studies (Blanco 1992, Goldberger 1989, Mackenzie 1988, Norman 1992, Stone 1994, Williams 1995)	1 RCT (see review of individual RCT) 6 observational studies (PGE ₂ versus comparison group) No of vaginal births Blanco 1992: 17 (81%, 95% CI 58% to 94%) versus 15 (71%, 95% CI 48% to 89%) Goldberger 1989: 18 (74%, 95% CI 51% to 87%) versus 46 (82%, 95% CI 72% to 92%) Mackenzie 1988: 329 (75%, 95% CI 71% to 79%) (no comparison group) Norman 1992: 22 (73%, 95% CI 54% to 88%) (no comparison group) Stone 1994: 60 (64%, 95% CI 54% to 74%) versus 598 (69%, 95% CI 66% to 72%) Williams 1995: 59 (50%, 95% CI 41% to 59%) versus 241 (68%, 95% CI 63% to 73%) Uterine rupture or dehiscence Blanco 1992: 0 versus 0 Goldberger 1989: 0 versus 0 Mackenzie 1988: 1 rupture, 4 dehiscence (no comparison group) Norman 1992: 0 (no comparison group) Stone 1994: 0 rupture and 2 dehiscence versus 0 Williams 1995: 0 versus 0	Source of Funding: none
McDonagh (2005) ⁶⁷	Study Type: Systematic review/ meta-analysis	2 RCTs (326 women)		Oral mifepristone 200 mg versus placebo (1 RCT)	Observational studies: compared with spontaneous labour, induction was more likely to result in	

Induction of labour

Bibliographic details	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
	Evidence level: 3	12 Observational studies (39170 women)		Weekly vaginal PGE ₂ versus expectant management (1 RCT, 12 observational studies)	caesarean delivery (20% [range 11–35%] versus 32% [range 18–44%]) Caesarean occurred in 24% (range 18–51%) of spontaneous labour compared with 48% (range 28–51%) of PGE ₂ induction There was a non-significant increase in uterine ruptures among those induced compared with spontaneous labour. There were no maternal deaths. Other maternal complications were infrequently and inadequately reported.	
Dodd (2004) ⁶⁶ Country: US, UK, France	Study Type: Systematic review/ meta-analysis Evidence level: 1++	3 RCTs (112 women)	Women with a previous caesarean birth, undergoing induction of labour.	Vaginal PGE ₂ 2.5 mg followed by amniotomy versus amniotomy + IV oxytocin (1 RCT) Vaginal misoprostol 25 µg 6-hourly versus IV oxytocin (1 RCT) Oral mifepristone 200 mg versus placebo (1 RCT)	Insufficient evidence (refer to review of individual RCT)	Source of Funding: not stated
Dodd (2006) ⁶⁵	Study Type: Systematic review/meta-analysis Evidence level: 1++	No RCT was identified.	Women with previous caesarean birth.	No RCTs was identified		Source of Funding: University of Adelaide, Australia
Rayburn (1999) ⁷² Country: US	Study Type: Randomised controlled trial Evidence level: 1+	Total number of patients = 294 Weekly PGE ₂ gel 0.5 mg, repeated at weekly office visits for up to three dose <i>n</i> = 143 Expectant management <i>n</i> = 151	Women at term who had one previous caesarean birth and unfavourable cervix (Bishop score < 6).	Weekly PGE ₂ gel 0.5 mg, repeated at weekly office visits for up to three dose versus expectant management.	Undelivered at 40 weeks: 34% versus 44% (NS) Undelivered at 41 weeks: 28% versus 24% (NS) Spontaneous vaginal birth: 49% versus 49% (NS) instrumental vaginal birth: 8% versus 6% (NS) CS: 43% versus 45% (NS) Uterine hyperstimulation: 0.7% versus 0% (NS) Uterine rupture: 0% versus 0% (NS) Maternal nausea and vomiting: 1.4% versus 1.3% (NS)	Source of Funding: Pharmacia & Upjohn Co, Kalamazoo, MI, US Computer-generated randomisation Blind to investigators Power calculation
Wing (1998) ⁷¹ Country: US	Study Type: Randomised Controlled Trial	Total number of patients = 38 vaginal misoprostol	women with a prior CS requiring induction of labour	vaginal misoprostol 25 µg 6-hourly (maximum 4 doses) vs	Uterine rupture : 12% vs 0% (RR 6.11, 95% CI 0.31 to 119.33) Apgar score < 7 at 5 minutes: 6% versus 0% (NS) Neonatal intensive care admission: 35% vs 19% (NS)	Source of Funding: not reported

Bibliographic details	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
	Evidence Level: 1-	25 µg at 6hourly interval (maximum 4 doses) <i>n</i> = 17 IV oxytocin <i>n</i> = 21		IV oxytocin		Method of randomisation and power calculation not reported The trial was stopped because of safety concerns
Taylor (1993) ⁷⁰ Country: UK	Study Type: Randomised controlled trial Evidence level: 1+	Total number of patients = 42 Vaginal PGE ₂ 2.5 mg followed by amniotomy <i>n</i> = 21 Amniotomy + IV oxytocin <i>n</i> = 21	Women with a previous caesarean birth, undergoing induction of labour because of prolonged pregnancy or pre-eclampsia (Bishop score < 9).	Vaginal PGE ₂ 2.5 mg followed by amniotomy vs amniotomy + IV oxytocin.	Induction to delivery interval (hr): 10.8 (4.2) versus 8.9 (2.4) (NS) Spontaneous vaginal birth: 57% versus 52% (NS) Operative vaginal birth: 24% versus 19%, 1.33 (95% CI 0.30 to 5.84) CS: 19% versus 29%, OR 0.59 (95% CI 0.14 to 2.49) Epidural usage: 81% versus 57%, OR 3.19 (95% CI 0.79 to 12.80) Apgar score < 7 at 5 minutes: 0 versus 0 (NS) Uterine rupture: 1/21 versus 0/21 (NS) Repeat CS: 0/4 versus 5/6 (<i>P</i> < 0.05)	Source of Funding: Not reported Randomisation using a predetermined code contained in sealed envelopes. No power calculation.
Chilaka (2004) ⁶⁰	Study Type: Non comparative case series Evidence level: 3	To determine the risk of uterine rupture.	Total number of women = 130	Women with a previous caesarean section undergoing induction of labour with PGE ₂ .	Spontaneous vaginal delivery: 65/130 (50%) Instrumental vaginal delivery: 14/130 (11%) CS: 51/130 (39%) Admission to NICU: 6/130 Neonatal death: 0 Suspected uterine rupture: 2 cases, not confirmed	
Kayani (2005) ⁶¹	Study Type: case series review of hospital delivery records Evidence level: 3	To estimate the risk of uterine rupture or dehiscence.	Total number of women = 205	Women with one previous caesarean section undergoing induction of labour (vaginal PGE ₂ <i>n</i> = 97; PGE ₂ + oxytocin <i>n</i> = 52; ARM <i>n</i> = 11; ARM + oxytocin <i>n</i> = 45	Spontaneous vaginal delivery: PGE ₂ : 47% PGE ₂ + oxytocin: 38.5% ARM only: 73% ARM + oxytocin: 62% Instrumental vaginal delivery: PGE ₂ : 10% PGE ₂ + oxytocin: 15.5% ARM only: 0 ARM + oxytocin: 13.5% CS: PGE ₂ : 43% PGE ₂ + oxytocin: 46%	

Induction of labour

Bibliographic details	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
					<p>ARM only: 27%</p> <p>ARM + oxytocin: 24.5%</p> <p>Uterine dehiscence:</p> <p>PGE₂: 0</p> <p>PGE₂ + oxytocin: 0</p> <p>ARM only: 0</p> <p>ARM + oxytocin: 2%</p> <p>Uterine rupture:</p> <p>PGE₂: 1%</p> <p>PGE₂ + oxytocin: 4%</p> <p>ARM only: 0</p> <p>ARM + oxytocin: 2%</p> <p>Adverse neonatal outcomes (seizures, death, admission to NICU, Apgar score < 7 at 5 minutes)</p> <p>PGE₂: 0</p> <p>PGE₂ + oxytocin: 1</p> <p>ARM only: 2</p> <p>ARM + oxytocin: 1</p>	
Grobman (2007) ⁶⁴	Study Type: Cohort	To compare pregnancy outcomes after induction with pregnancy outcomes after spontaneous labour.	<p>Total number of women = 11 778</p> <p>With with no prior vaginal delivery (<i>n</i> = 6132)</p> <p>With with prior vaginal delivery (<i>n</i> = 5646)</p>	Women with one previous caesarean birth undergoing induction of labour.	<p>In women with no prior vaginal delivery</p> <p>Vaginal birth: induced vs apontaneous labour 51% versus 64.7% (OR 0.57, 95% CI 0.51 to 0.63)</p> <p>Uterine rupture: induced vs apontaneous labour 1.5% vs 0.8% (OR 1.84, 95% CI 1.11 to 3.05)</p> <p>Uterine rupture: induced with PGE₂:0%</p> <p>Uterine rupture: induced with oxy: 1.8%</p> <p>Uterine rupture: induced with oxy + PGE₂: 1.2%</p> <p>prior vaginal delivery</p> <p>Vaginal birth: induced vs apontaneous labour 83.3% versus 88.3% (OR 0.66, 95% CI 0.56 to 0.78)</p> <p>Uterine rupture: induced vs apontaneous labour 0.6% vs 0.4% (OR 1.39, 95% 0.62 to 3.13)</p> <p>Uterine rupture: induced with PGE₂:0%</p> <p>Uterine rupture: induced with oxy: 0.6%</p> <p>Uterine rupture: induced with oxy + PGE₂: 0.5%</p>	Funding: National Institute of Child Health , US

4.5 Maternal request for induction of labour

Bibliographic details	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
Cole (1975) ⁸⁰ Country: UK	Study Type: Randomised controlled trial Evidence level: 1+	Total number of women = 228 Elective induction of labour (forewater amniotomy followed by IV oxytocin) <i>n</i> = 111 Expectant management <i>n</i> = 117	pregnant women at 39–40 weeks of gestation (mixed parity)	elective induction of labour (forewater amniotomy followed by IV oxytocin) vs expectant management	Spontaneous birth: 65% versus 70% (NS) Forceps births: 31% versus 22% (NS) CS: 5% versus 8% (NS) Mean length of labour (hrs): 6.4 (3.1) versus 7.0 (3.4) (NS) Mean dose of pethidine (mg): 157 versus 155 (NS) Number of epidurals: 22 versus 14 (NS) Mean blood loss after vaginal birth (ml): 185 (139) versus 233 (150) (<i>P</i> = 0.05)	Source of Funding: not stated Methods of randomisation and power calculation not reported.
Breart (1982) ⁷⁹ Country: France	Study Type: Randomised controlled trial Evidence Level: 1+	Total number of women = 716 Elective induction of labour (oxytocin and AROM) <i>n</i> = 481 expectant management (fetal heart rate checking and amnioscopy every 2–3 days) <i>n</i> = 235	Women with low risk pregnancy at 37–39 weeks of gestation (no indication or contraindication for induction of labour).	Elective induction of labour (oxytocin and AROM) vs expectant management (fetal heart rate checking and amnioscopy every 2–3 days)	CS: 4% versus 7% (NS) Assisted vaginal births: 26% versus 15%, RR 1.74 (95% CI 1.24 to 2.45)	Source of Funding: not reported Randomised, allocation using envelopes (2:1 allocation) Power calculation not clear 36% of the intervention group and 86% of the control group followed the trial protocol.

4.6 Breech presentation

Bibliographic Information	Study type and evidence level	Aim of study	Number of patients and patient characteristics	Population characteristics	Outcome measures	Reviewer comments
Rojansky (2001) ⁸⁶ Country: Israel	Study Type: Case-control Study Evidence level: 2-	To assess effects of breech induction.	Total number of women = 175	Women with breech presentation.	Vaginal birth: 66% versus 68% versus 0% (NS) CS: 34% versus 32% versus 100% (NS) Apgar score < 7: 0% versus < 1% versus 0% (NS)	Funding: not stated
Fait (1998) ⁸⁵	Study Type: retrospective matched-paired study Evidence level: 2-	Assess the effects of breech induction.	Total number of women = 69 Breech induction (extra-amniotic saline and concomitant oxytocin) <i>n</i> = 23 Vertex induction <i>n</i> = 46	Women with breech presentation.	Vaginal birth: 52% versus 83%, OR 0.23 (95% CI 0.07 to 0.8) Caesarean birth rate: 48% versus 17%, OR 4.3 (95% CI 1.3 to 15.6) Rates of Apgar score, birth trauma and maternal morbidity were similar in the groups.	

4.7 Fetal growth restriction

Bibliographic details	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
Van den Hove (2006) ⁵⁹	Study Type: Randomised controlled trial	Total number of patients = 33	Women with fetal growth restriction at term.	Induction of labour (PGE ₂ gel for cervical priming and amniotomy and IV oxytocin)	Obstetric interventions (spontaneous birth, forceps, vacuum, CS): 25% versus 24% (NS)	Source of Funding: not reported
Country: The Netherlands	Evidence level: 1+	induction of labour <i>n</i> = 16 Expectant management <i>n</i> = 17		versus expectant management.	Neonatal morbidity: 50% versus 35% (NS)	Allocation by statistician at random and put in consecutively numbered envelopes. No power calculation.

4.9 Intrauterine fetal death

Bibliographic details	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
Irion (1998) ¹⁰⁷ Country: Israel, US	Study Type: Systematic review/meta-analysis Evidence level: 1++	2 RCTs (313 women)	Non-diabetic women with suspected fetal macrosomia, for induction of labour.	Induction of labour (with prostaglandins and IV oxytocin) versus expectant management.	<u>Induction of labour versus expectant management (2 RCTs)</u> Caesarean birth: 22/153 versus 38/160, RR 0.88 (95% CI 0.59 to 1.34) Instrumental birth: 17/153 versus 18/160, RR 0.98 (95% CI 0.53 to 1.82) Spontaneous birth: 104/153 versus 104/160, RR 1.05 (95% CI 0.89 to 1.22) Third and fourth degree perineal tear: 0 Mean birthweight: WMD -61.44 (95% CI -132.00 to 11.12) Low Apgar score (5 minutes): 0 Shoulder dystocia: 9/153 versus 9/160, RR 1.06 (95% CI 0.44 to 2.56) Brachial plexus injury: 0/153 versus 2/160, RR 0.21 (95% CI 0.01 to 4.28) Fracture (any): 0/153 versus 4/160, RR 0.12 (95% CI 0.01 to 2.12) Admission to neonatal intensive care unit: 0 Intracranial haemorrhage: 3/63 versus 2/52, RR 1.06 (95% CI 0.19 to 5.96) Convulsions: 0 Perinatal mortality: 0	Source of Funding: University of Geneva
Cabrol (1990) ⁹⁰ Country: France and South Africa	Study Type: Randomised controlled trial Evidence level: 1+	Mifepristone 600 mg (200 mg three times a day) for 2 days <i>n</i> = 48 Placebo for 2 days <i>n</i> = 46	Women (mean age between 27.8–28.9 years) with a gestational age > 16 weeks (mean 197–199 days of amenorrhoea) and absence of signs of imminent labor based in obstetric and gynecology departments.	Mifepristone 600 mg (200 mg three times a day) for 2 days versus placebo.	Labour within 72 hours: 63% versus 17.4% (<i>P</i> < 0.001) Uterine bleeding: 3/46 vs 0 Nausea and vomiting: 2/46 vs 0	Source of Funding: One author associated with Roussel Uclaf Sample size calculation attempted, reported double-blind but not clear who was blind. Randomisation obtained by the method of random permutations. Allocation concealment unclear Two women from the Mifepristone group were excluded after randomisation.
Sanchez-Ramos (2002) ¹⁰⁸	Study Type: Systematic review/meta-analysis	2 RCTs, 9 observational studies.	Women with suspected fetal macrosomia.	Expectant management versus induction of labour.	<u>2 RCTs</u> CS: OR 1.17 (95% CI 0.69 to 2.01) Spontaneous vaginal birth: OR 0.90 (95% CI 0.54 to 1.48)	Source of Funding: Not stated.

Bibliographic details	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
Country: US, Europe	Evidence level: 2+				Operative vaginal birth: OR 1.02 (95% CI 0.50 to 2.08) Rate of shoulder dystocia: OR 0.93 (95% CI 0.35 to 2.46)	
					<u>9 Observational studies</u> CS: OR 0.39 (95% CI 0.30 to 0.50) Spontaneous vaginal birth: OR 2.07 (95% CI 1.34 to 3.19) Operative vaginal birth: OR 0.89 (95% CI 0.68 to 1.17) Rate of shoulder dystocia: OR 0.81 (95% CI 0.50 to 1.31)	

5 Methods of induction of labour

5.1 Pharmacological-based methods

Bibliographic Information	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
Kelly (2003) ¹⁰⁹ Country: UK, US, Europe, Australia, New Zealand	Study Type: Systematic review/meta-analysis Evidence level: 1++	10039 women (57 RCTs)	Women requiring induction of labour, mixed parity mixed Bishop score.	Vaginal PGE ₂ gel versus placebo/no treatment (35 RCTs)	<u>Vaginal PGE₂ versus placebo/no treatment (all women)</u> Vaginal delivery not achieved within 24 hours (2 RCTs): 18% versus 99% RR 0.19 (95% CI 0.14 to 0.25) Caesarean birth: RR 0.89 (95% CI 0.79 to 1.00) Uterine hyperstimulation with FHR (13 RCTs): 4.6% versus 0.51%, RR 4.14 (95% CI 1.93 to 8.90)	CESU, RCOG
				Vaginal PGF _{2α} versus placebo (3 RCTs)	<u>Vaginal PGF_{2α} versus placebo</u> Caesarean birth: (NS) Improved cervical score (5 RCTs): 15% versus 60%, RR 0.25 (95% CI 0.13 to 0.49) Oxytocin augmentation (11 RCTs): 53.9% versus 89%, RR 0.60 (95% CI 0.43 to 0.84)	
				Vaginal PGF _{2α} versus PGE ₂ (2 RCTs)	<u>Comparisons of vaginal PGE₂ and PGF_{2α}. PGE₂ tablet, gel and pessary</u> Insufficient data to make meaningful conclusions appeared to be efficacious as each other.	
				Vaginal PGE ₂ gel versus PGE ₂ tablet (5 RCTs)	<u>Lower dose versus higher dose regimens (NS)</u>	
				Vaginal PGE ₂ gel versus PGE ₂ pessary/suppository (2 RCTs)	<u>PGE₂ versus placebo/no treatment (all women, unfavourable cervix)</u>	
				Vaginal PGE ₂ tablet versus PGE ₂ pessary/suppository (3 RCTs)	Vaginal delivery not achieved within 24 hours (1 RCT): RR 0.88 (95% CI 0.67 to 1.15) Uterine hyperstimulation with FHR changes (12 RCTs): RR 4.47 (95% CI 2.01 to 9.93)	
				Vaginal PGE ₂ (slow release) versus PGE ₂ (any vehicle) (7 RCTs)	Caesarean birth (22 RCTs): RR 0.87 (95% CI 0.75 to 1.02)	
				Vaginal PGE ₂ low dose versus PGE ₂ high dose (7 RCTs)		

Bibliographic Information	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
				RCTs)	<p>Serious neonatal morbidity or perinatal death (4 RCTs): 0</p> <p>Serious maternal morbidity or death (2 RCTs): RR 4.84 (95% CI 0.24 to 96.66)</p> <p>Cervix unfavourable/ unchanged after 12–24 hours (2 RCTs): RR 0.53 (95% CI 0.35 to 0.79)</p> <p>Oxytocin augmentation (8 RCTs): RR 0.72 (95% CI 0.61 to 0.85)</p> <p>Uterine hyperstimulation without FHR changes (9 RCTs): RR 2.63 (95% CI 0.99 to 7.01)</p> <p>Uterine rupture (1 RCT): RR 2.90 (95% CI 0.12 to 68.50)</p> <p>Epidural analgesia (5 RCTs): RR 1.46 (95% CI 1.22 to 1.75)</p> <p>Instrumental vaginal birth (7 RCTs): RR 0.88 (95% CI 0.61 to 1.27)</p> <p>Meconium-stained liquor (5 RCTs): RR 0.65 (95% CI 0.47 to 0.89)</p> <p>Apgar score < 7 at 5 minutes (11 RCTs): RR 1.08 (95% CI 0.59 to 1.99)</p> <p>Neonatal intensive care admission (7 RCTs): RR 0.80 (95% CI 0.51 to 1.27)</p> <p>Perinatal death (3 RCTs): 0</p> <p>Maternal side effects (all) (10 RCTs): RR 1.08 (95% CI 0.73 to 1.59)</p> <p>Maternal nausea (1 RCT): 0</p> <p>Maternal vomiting (2 RCTs): RR 0.97 (95% CI 0.15 to 6.41)</p> <p>Maternal diarrhoea (3 RCTs): 0</p> <p>Other maternal side effects (7 RCTs): RR 0.97 (95% CI 0.62 to 1.51)</p> <p>Postpartum haemorrhage (7 RCTs): RR 0.99 (95% CI 0.47 to 2.05)</p> <p>Serous maternal complications (1 RCT): RR 2.90 (95% CI 0.12 to 68.50)</p> <p><u>PGE₂ versus placebo/no treatment (primiparous women, unfavourable cervix)</u></p> <p>Vaginal delivery not achieved within 24 hours (1 RCT): RR 0.88 (95% CI 0.67 to 1.15)</p> <p>Uterine hyperstimulation with FHR changes (3 RCTs): RR 3.00 (95% CI 0.13 to 68.57)</p> <p>Caesarean birth (8 RCTs): RR 0.88 (95% CI 0.66 to 1.17)</p> <p>Serious neonatal morbidity or perinatal death (2 RCTs): 0</p>	

Induction of labour

Bibliographic Information	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
					<p>Serious maternal morbidity or death (1 RCT): 0 Oxytocin augmentation (3 RCTs): RR 0.59 (95% CI 0.47 to 0.73) Uterine hyperstimulation without FHR changes (2 RCTs): RR 0.35 (95% CI 0.02 to 8.10) Epidural analgesia (3 RCTs): RR 1.95 (95% CI 1.50 to 2.54) Instrumental vaginal birth (3 RCTs): RR 0.94 (95% CI 0.60 to 1.47) Meconium-stained liquor (2 RCTs): RR 0.57 (95% CI 0.29 to 1.13) Apgar score < 7 at 5 minutes (3 RCTs): RR 0.74 (95% CI 0.17 to 3.27) Neonatal intensive care admission (3 RCTs): RR 1.06 (95% CI 0.54 to 2.09) Perinatal death (1 RCT): 0 Maternal side effects (all) (2 RCTs): RR 0.87 (95% CI 0.50 to 1.50) Other maternal side effects (2 RCTs): 0.87 (95% CI 0.50 to 1.50) Postpartum haemorrhage (2 RCTs): RR 0.67 (95% CI 0.24 to 1.84)</p>	
					<p><u>PGE₂ versus placebo/no treatment (multiparous women, unfavourable cervix)</u> Uterine hyperstimulation with FHR changes (1 RCT): 0 Caesarean birth (2 RCTs): RR 1.95 (95% CI 0.30 to 12.59)</p>	
					<p><u>PGE₂ versus placebo/no treatment (all women, favourable cervix)</u> Vaginal delivery not achieved within 24 hours (1RCT) RR 0.12, 95 % CI 0.08 to 0.17</p>	
					<p><u>PGF_{2α} versus placebo/no treatment (unfavourable cervix)</u> Uterine hyperstimulation with FHR changes (1 RCT): RR 3.00 (95% CI 0.13 to 68.57) Caesarean birth (1 RCT): RR 0.33 (95% CI 0.04 to 2.87) Oxytocin augmentation (1 RCT): RR 0.88 (95% CI 0.73 to 1.05) Epidural analgesia (1 RCT): RR 0.85 (95% CI 0.56 to 1.27)</p>	
					<p><u>PGF_{2α} versus PGE₂ (all women, unfavourable cervix)</u> Vaginal delivery not achieved within 24 hours (1 RCT): RR 0.51 (95% CI 0.05 to 5.42)</p>	

Bibliographic Information	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
					<p>Uterine hyperstimulation with FHR changes (2 RCTs): RR 1.00 (95% CI 0.07 to 14.64)</p> <p>Caesarean birth (2 RCTs): RR 1.02 (95% CI 0.47 to 2.22)</p> <p>Oxytocin augmentation (1 RCT): RR 2.33 (95% CI 1.21 to 4.51)</p> <p>Epidural analgesia (1 RCT): RR 1.57 (95% CI 0.82 to 3.00)</p> <p>Apgar score < 7 at 5 minutes (1 RCT): RR 0.21 (95% CI 0.01 to 4.14)</p> <p><u>PGF_{2α} versus PGE₂ (primiparous women, unfavourable cervix)</u></p> <p>Uterine hyperstimulation with FHR changes (1 RCT): RR 1.00 (95% CI 0.07 to 14.64)</p> <p>Caesarean birth (1 RCT): RR 1.00 (95% CI 0.07 to 14.64)</p> <p>Oxytocin augmentation (1 RCT): RR 2.33 (95% CI 1.21 to 4.51)</p> <p>Epidural analgesia (1 RCT): RR 1.57 (95% CI 0.82 to 3.00)</p> <p><u>PGE₂ gel versus PGE₂ tablet (all women, unfavourable cervix)</u></p> <p>Maternal and fetal outcomes (4 RCTs): NS</p> <p><u>PGE₂ gel versus PGE₂ tablet (primiparous women, unfavourable cervix)</u></p> <p>Maternal and fetal outcomes (3 RCTs): NS (No pooled data for multiparous women)</p> <p><u>PGE₂ gel versus PGE₂ suppositories/pessary (all women, unfavourable cervix)</u></p> <p>Uterine hyperstimulation with FHR changes: RR 0.16 (95% CI 0.03 to 0.87)</p> <p>Other maternal and fetal outcomes (2 RCTs): NS (No pooled data for primiparous and multiparous women)</p> <p><u>PGE₂ tablet versus PGE₂ suppositories/pessary (all women, unfavourable cervix)</u></p> <p>Oxytocin augmentation was less likely to occur with the use of PGE₂ tablet when compared with PGE₂ suppositories/pessary. other maternal and fetal outcomes (3 RCTs): NS</p> <p>PGE₂ (controlled release) versus all PGE₂ delivery systems (all women, unfavourable cervix)</p> <p>Oxytocin augmentation: RR 0.55 (95% CI 0.35 to 0.88)</p> <p>Other maternal and fetal outcomes (4 RCTs): NS</p>	

Induction of labour

Bibliographic Information	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
					<p><u>PGE₂ (controlled release) versus all PGE₂ delivery systems (primiparous women, unfavourable cervix)</u> Oxytocin augmentation: RR 0.44 (95% CI 0.22 to 0.91) Other maternal and fetal outcomes (2 RCTs): NS</p> <p><u>PGE₂ (controlled release) versus all PGE₂ delivery systems (multiparous women, unfavourable cervix)</u> Oxytocin augmentation: RR 0.41 (95% CI 0.20 to 0.86) Other maternal and fetal outcomes (1 RCT): NS</p> <p><u>PGE₂ low dose versus PGE₂ high dose (all women, unfavourable cervix)</u> Uterine hyperstimulation with FHR changes: RR 0.18 (95% CI 0.03 to 0.99) Other maternal and fetal outcomes (4 RCTs): NS</p>	
El-Shawarby (2006) ¹¹⁰	Study Type: RCT Evidence level: 1-	72 women undergoing induction of labour	Women undergoing induction of	Controlled-release PGE ₂ pessary (Proress) (n = 34) versus Vag PGE ₂ gel (Prostin)	No of preparations used: 1.4 (1-3) vs 1.9 (1-4) (P < 0.05) Spontaneous vaginal delivery: 73% vs 66% (NS) Instrumental delivery: 12% vs 26% (NS) CS: 15% vs 8% (NS) Epidural usage: 38% vs 32% (NS) Time to delivery (hours): 25 vs 23 (NS)	Not stated Randomisation using 'sealed envelopes', no further details of allocation concealment given Power calculation not reported Not ITT Drop-out rate: 28%
French (2001) ¹¹³	Study Type: Systematic review/meta-analysis Evidence level: 1++	2688 women (19 RCTs)	Women requiring induction of labour, Bishop score =3 to 7.	Oral PGE ₂ versus no treatment or placebo (3 RCTs, 195 women) Oral PGE ₂ versus vaginal PGE ₂ (3 RCTs, 108 women) Oral PGE ₂ versus cervical	<u>PGE₂ versus no treatment</u> CS (3 RCTs): RR 0.54 (95% CI 0.29 to 0.98) <u>PGE₂ versus vs other treatments: CS (NS)</u> <u>PGE₂ versus all oxytocin</u> Vaginal delivery not achieved within 24 hours (3 RCTs): RR 1.97 (95% CI 0.86 to 4.48)	None stated

Bibliographic Information	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
				PGE ₂ (2 RCTs, 80 women)	Uterine hyperstimulation with FHR changes (4 RCTs): RR 7.0 (95% CI 0.37 to 132.22) Perinatal death (1 RCT): Two deaths due to congenital malformations	
				Oral PGE ₂ versus intravenous oxytocin (7 RCTs, 779 women)	Serious maternal morbidity (1 RCT): None Gastrointestinal side effects, nausea and vomiting (19 RCTs): Significantly more reported in the PGE ₂ group	
				Oral PGE ₂ versus intravenous oxytocin + amniotomy (4 RCTs, 435 women)	Oxytocin augmentation (3 RCTs): Oxytocin needed more in the no treatment group Uterine hyperstimulation without FHR changes (8 RCTs): NS Epidural analgesia (3 RCTs): NS Instrumental vaginal delivery (17 RCTs): NS	
				Oral PGE ₂ versus oral oxytocin (4 RCTs, 822 women)	Meconium-stained liquor (2 RCTs): NS Apgar score < 7 at 5 minutes (7 RCTs): NS Admission to NICU (1 RCT): NS Postpartum haem (6 RCTs): NS	
				Oral PGE ₂ versus oral oxytocin + amniotomy (2 RCTs, 223 women) and	Maternal and neonatal infection requiring antibiotics (1 RCT, prelabour rupture of membranes): A trend favouring oral PGE ₂ group for use of antibiotics Women's satisfaction (1 RCT): Women preferred oral treatment than intravenous medication	
				Oral PGE ₂ dose incremental or high dose versus oral PGE ₂ constant or low dose (2 RCTs, 46 women)	Carer's satisfaction (1 RCT): No clear preference <u>Oral prostaglandins versus placebo/no treatment (unfavourable cervix)</u> Caesarean birth (3 RCTs): RR 0.54 (95% CI 0.29 to 0.98) Uterine hyperstimulation without FHR changes (2 RCTs): RR 4.00 (95% CI 0.46 to 34.81) Instrumental vaginal birth (1 RCT): RR 1.25 (95% CI 0.47 to 3.33) <u>Oral prostaglandins versus vaginal prostaglandins (unfavourable cervix)</u> Caesarean birth (2 RCTs): RR 0.69 (95% CI 0.33 to 1.47) Cervix unfavourable/unchanged after 12–24 hours (1 RCT): RR 2.13 (95% CI 0.21 to 21.22) Instrumental vaginal birth (3 RCTs): RR 0.82 (95% CI 0.44 to 1.54) <u>Oral prostaglandins versus intracervical prostaglandins</u>	

Induction of labour

Bibliographic Information	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
					<p><u>(unfavourable cervix)</u> Caesarean birth (1 RCT): RR 0.63 (95% CI 0.24 to 1.65) Instrumental vaginal birth (1 RCT): RR 1.25 (95% CI 0.38 to 4.12) Apgar score < 7 at 5 minutes (RCT): RR 1.00 (95% CI 0.07 to 15.12)</p> <p><u>Oral prostaglandins versus oral oxytocin (unfavourable cervix)</u> Caesarean birth (1 RCT): RR 2.22 (95% CI 0.70 to 7.02) Oxytocin augmentation (1 RCT): RR 0.63 (95% CI 0.28 to 1.41) Instrumental vaginal birth (1 RCT) : RR 0.87 (95% CI 0.45 to 1.67) Apgar score < 7 at 5 minutes (1 RCT): RR 1.97 (95% CI 0.18 to 21.46)</p> <p><u>Oral prostaglandins versus intravenous oxytocin (unfavourable cervix)</u> Caesarean birth (3 RCTs): RR 1.05 (95% CI 0.53 to 2.09) Uterine hyperstimulation without FHR changes (1 RCT): RR 0.20 (95% CI 0.01 to 4.06) Instrumental vaginal birth (2 RCTs): RR 0.85 (95% CI 0.43 to 1.68) Apgar score < 7 at 5 minutes (1 RCT): RR 1.00 (95% CI 0.06 to 15.53) Gastrointestinal effects (1 RCT): RR 5.00 (95% CI 0.61 to 41.22) Postpartum haemorrhage (1 RCT): RR 0.11 (95% CI 0.01 to 2.01)</p>	
Luckas (2000) ¹¹⁴	Study Type: Systematic review/meta-analysis Evidence level: 1++	1165 women (13 RCTs)	Women requiring induction of labour, mixed Bishop score.	Intravenous PGE ₂ versus intravenous oxytocin (4 RCTs) Intravenous PGE ₂ versus extra-amniotic prostaglandin infusion (1 RCT) Intravenous PGF _{2α} versus intravenous oxytocin (8 RCTs)	<p><u>Intravenous prostaglandins versus IV oxytocin</u> Uterine hyperstimulation with changes in the fetal heart rate: RR 6.76 (95% CI 1.23 to 37.11) Uterine hyperstimulation without changes in the fetal heart rate: RR 4.25 (95% CI 1.48 to 12.24) Maternal side effects, such as gastrointestinal, thrombophlebitis and pyrexia: RR 3.75 (95% CI 2.46 to 5.70) Combination of oxytocin/PGF_{2α} and oxytocin or extra-amniotic PGE₂: No significant differences in maternal or fetal outcomes reported</p> <p><u>Intravenous PGE₂ versus intravenous oxytocin (primiparous</u></p>	None stated

Bibliographic Information	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
					<p>women with unfavourable cervix) Vaginal delivery not achieved within 24 hours (1 RCT): RR 0.71 (95% CI 0.24 to 2.10) Caesarean births (1 RCT): RR 0.71 (95% CI 0.24 to 2.10) Serious maternal morbidity or death: (1 RCT) 0</p> <p><u>Intravenous PGF_{2α} versus intravenous oxytocin (multiparous women with unfavourable cervix)</u> Vaginal delivery not achieved within 24 hours (1 RCT): RR 3.00 (95% CI 0.33 to 26.92)</p>	
Hutton (2001) ¹¹⁵	Study Type: Systematic review/meta-analysis Evidence level: 1++	920 women (10 RCTs)	Mixed parity and Bishop score.	<p>Extra-amniotic prostaglandin E2 versus extra-amniotic placebo: 3 RCTs</p> <p>Extra-amniotic PGF_{2α} versus extra-amniotic placebo gel: 1 RCT</p> <p>Extra-amniotic prostaglandin E2 versus vaginal prostaglandin: 4 RCTs</p> <p>Extra-amniotic prostaglandin E2 versus intravenous oxytocin: 1 RCT</p> <p>Extra-amniotic PGF_{2α} versus mechanical method (Foley catheter): 1 RCT</p>	<p>Extra-amniotic prostaglandins versus placebo Oxytocin use to initiate or augment labour: RR 0.50 (95% CI 0.38 to 0.66) All other maternal and fetal outcomes comparable.</p> <p><u>Extra-amniotic prostaglandin E2 versus extra-amniotic placebo (in women with unfavourable cervix)</u> Uterine hyperstimulation with FHR changes: (1 RCT) 0 Caesarean birth (3 RCTs): RR 0.47 (95% CI 0.20 to 1.08) Oxytocin augmentation (3 RCTs): RR 0.50 (95% CI 0.38 to 0.66) Uterine hyperstimulation without FHR changes (2 RCTs): RR 7.00 (95% CI 0.37 to 132.40) Instrumental vaginal birth (1 RCT): RR 1.40 (95% CI 0.56 to 2.35) Maternal side effects (2 RCTs): RR 5.00 (95% CI 0.26 to 96.13)</p> <p><u>Extra-amniotic PGF_{2α} versus extra-amniotic placebo (in women with unfavourable cervix)</u> Caesarean birth (1 RCT): RR 0.33 (95% CI 0.03 to 3.20) Serious maternal morbidity or death (1 RCT): RR 2.06 (95% CI 0.09 to 46.11) Uterine hyperstimulation without FHR changes (1 RCT): RR 2.06 (95% CI 0.09 to 46.11) Instrumental vaginal birth (1 RCT): RR 0.57 (95% CI 0.27 to 1.20) Perinatal death (1 RCT): RR 2.06 (95% CI 0.09 to 46.11)</p> <p><u>Extra-amniotic PGF_{2α} versus extra-amniotic placebo (in primiparous women with unfavourable cervix)</u> Same as above</p>	None stated

Induction of labour

Bibliographic Information	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
					<p><u>Extra-amniotic prostaglandin E2 versus vaginal PGE₂ (women with unfavourable cervix)</u></p> <p>Vaginal delivery not achieved in 24 hours (1 RCT): RR 1.05 (95% CI 0.81 to 1.36)</p> <p>Uterine hyperstimulation with FHR changes (1 RCT): 0</p> <p>Caesarean birth (3 RCTs): RR 0.89 (95% CI 0.42 to 1.89)</p> <p><u>Extra-amniotic prostaglandin E2 versus vaginal PGE₂ (in primiparous women with unfavourable cervix)</u></p> <p>Vaginal delivery not achieved in 24 hours (1 RCT): RR 1.03 (95% CI 0.73 to 1.45)</p>	
Boulvain (2008) ¹¹⁶	Study Type: Systematic review/meta-analysis Evidence level: 1++	7738 women (56 RCTs)	Mixed parity and Bishop score.	<p>Intracervical PGE₂ vs placebo</p> <p>Intracervical PGE₂ vs intravaginal PGE₂</p> <p>Intracervical PGE₂ vs</p>	<p>In women with unfavourable cervix</p> <p><u>Intracervical PGE₂ vs placebo/no treatment:</u></p> <p>Vaginal delivery not achieved in 24 hours (4 RCTs): RR 0.61 (95% CI 0.47 to 0.79)</p> <p>Uterine hyperstimulation with FHR changes (12 RCTs): RR 1.21 (95% CI 0.72 to 2.05)</p> <p>Caesarean section (27 RCTs): RR 0.88 (95% CI 0.77 to 1.01)</p> <p>Serious neonatal morbidity or perinatal death (4 RCTs): RR 0.75 (95% CI 0.19 to 2.96)</p> <p>Serious maternal morbidity or death (2 RCTs): RR 0.33 (95% CI 0.01 to 7.96)</p> <p>Cervix unfavourable/unchanged after 12–24 hours (1 RCT): 0</p> <p>Oxytocin augmentation (1 RCT): RR 0.67 (95% CI 0.40 to 1.12)</p> <p>Uterine hyperstimulation without FHR changes (11 RCTs): RR 1.59 (95% CI 1.09 to 2.33)</p> <p>Instrumental vaginal delivery (7 RCTs): RR 1.03 (95% CI 0.70 to 1.50)</p> <p>Meconium-stained liquor (3 RCTs): RR 1.20 (95% CI 0.80 to 1.81)</p> <p>Apgar score < 7 at 5 minutes (14 RCTs): RR 0.91 (95% CI 0.2 to 1.34)</p> <p>Neonatal intensive care admission (4 RCTs): RR 0.32 (95% CI 0.10 to 1.07)</p> <p>Perinatal death (2 RCTs): RR 0.20 (95% CI 0.01 to 4.05)</p> <p>Maternal side effects (all) (10 RCTs): RR 1.18 (95% CI 0.95 to 1.47)</p> <p>Maternal nausea (3 RCTs): RR 2.00 (95% CI 0.19 to 21.47)</p> <p>Maternal vomiting (4 RCTs): RR 2.27 (95% CI 1.11 to 4.63)</p>	

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					Maternal diarrhoea (3 RCTs): RR 1.13 (95% CI 0.23 to 5.65) Post Partum haemorrhage (4 RCTs): RR 3.27 (95% CI 0.82 to 13.03) Serious maternal complications (1 RCT): RR 1.05 (95% CI 0.22 to 4.90) Maternal death (1 RCT): RR 0.09 (95% CI 0.00 to 1.60)	
					<u>In women with unfavourable cervix</u> <u>Intracervical PGE₂ vs vaginal PGE₂:</u> Vaginal delivery not achieved in 24 hours (10 RCTs): RR 1.26, 95% CI 1.12 to 1.42) Uterine hyperstimulation with FHR changes (12 RCTs): RR 0.85 (95% CI 0.42 to 1.73) Caesarean section (26 RCTs): RR 1.06 (95% CI 0.93 to 1.21) Serious neonatal morbidity or perinatal death (1 RCT): 0 Serious maternal morbidity or death (2 RCTs): RR 3.07 (95% CI 0.13 to 74.71) Oxytocin augmentation (9 RCTs): RR 0.96 (95% CI 0.85 to 1.10) Uterine hyperstimulation without FHR changes (10 RCTs): RR 0.82 (95% CI 0.56 to 1.21) Uterine rupture (1 RCT): RR 3.07 (95% CI 0.13 to 74.71) Epidural analgesia (1 RCT): RR 1.06 (95% CI 0.91 to 1.24) Instrumental vaginal delivery (9 RCTs): RR 0.91 (95% CI 0.69 to 1.20) Meconium-stained liquor (2 RCTs): RR 0.90 (95% CI 0.41 to 1.97) Apgar score < 7 at 5 minutes (13 RCTs): RR 0.93 (95% CI 0.49 to 1.74) Maternal side effects (all) (10 RCTs): RR 1.17 (95% CI 0.91 to 1.50) Maternal nausea (2 RCTs): RR 0.90 (95% CI 0.54 to 1.50) Maternal vomiting (3 RCTs): RR 1.17 (95% CI 0.66 to 2.06) Maternal diarrhoea (4 RCTs): RR 4.94 (95% CI 0.86 to 28.54) Post Partum haemorrhage (2 RCTs): RR 1.71 (95% CI 0.23 to 12.66) Serious maternal complications (1 RCT): 0 Women not satisfied (1 RCT): RR 0.64 (95% CI 0.11 to 3.67)	
					<u>Women with a favourable cervix</u>	

Induction of labour

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					<p><u>Intracervical PGE₂ vs placebo/no treatment:</u> No data</p> <p><u>Intracervical PGE₂ vs vaginal PGE₂:</u> Caesarean section (1 RCT): RR 2.10 (95% CI 0.20 to 22.55) Instrumental vaginal delivery (1 RCT): RR 0.93 (95% CI 0.49 to 1.76)</p>	
Kelly (2001) ¹¹⁷ Country: US, UK, Europe, Canada, Australia, New Zealand	Study Type: Systematic review/meta-analysis Evidence Level: 1++	58 RCTs, 11 129 women	Mixed parity and Bishop score.	<p>Intravenous oxytocin versus expectant management (26 RCTs, 6660 women)</p> <p>Intravenous oxytocin versus vaginal prostaglandins (27 RCTs, 4649 women)</p>	<p><u>Intravenous oxytocin versus expectant management (in women with an unfavourable cervix)</u> Vaginal delivery not achieved within 24 hours (1 RCT): RR 0.17 (95% CI 0.09 to 0.33) Caesarean birth (13 RCTs): RR 1.20 (95% CI 0.89 to 1.62) Serious neonatal morbidity or prenatal death, excluding congenital anomalies (6 RCTs): RR 1.03 (95% CI 0.21 to 4.97) Serious maternal morbidity or death (1 RCT): 0 Uterine hyperstimulation without FHR changes (1 RCT): 0 Epidural analgesia (3 RCTs): RR 0.89 (95% CI 0.69 to 1.16) Instrumental vaginal birth (5 RCTs): RR 1.15 (95% CI 0.73 to 1.83) Meconium-stained liquor (1 RCT): RR 1.33 (95% CI 0.34 to 5.21) Apgar score < 7 at 5 minutes (5 RCTs): RR 0.37 (95% CI 0.09 to 1.50) Neonatal intensive care unit admission (1 RCT): RR 3.51 (95% CI 1.34 to 9.22) Perinatal death, excluding major congenital anomalies (5 RCTs): RR 1.00 (95% CI 0.15 to 6.85) Post partum haemorrhage(2 RCTs): RR 2.00 95% CI 0.38 to 10.60) Chorioamnionitis (6 RCTs): RR 1.49 (95% CI 1.06 to 2.10) Endometritis (6 RCTs): RR 0.67 (95% CI 0.36 to 1.28) Neonatal infection (7 RCTs): RR 0.35 (95% CI 0.13 to 0.96) Neonatal antibiotics (1 RCT): RR 3.36 (95% CI 1.13 to 10.01) Neonatal jaundice (2 RCTs): RR 0.88 (95% CI 0.43 to 1.80) Neonatal respiratory distress syndrome (1 RCT): RR 0.86 (95% CI 0.24 to 3.10)</p> <p><u>Intravenous oxytocin versus vaginal PGE₂ (in women with an unfavourable cervix)</u> Vaginal delivery not achieved within 24 hours (4 RCT): RR 1.85</p>	CESU, RCOG

Bibliographic Information	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
					<p>(95% CI 1.41 to 2.43)</p> <p>Uterine hyperstimulation with FHR changes (2 RCT): RR 0.36 (95% CI 0.01 to 8.69)</p> <p>Caesarean birth (16 RCTs): RR 1.27 (95% CI 0.95 to 1.68)</p> <p>Serious neonatal morbidity or prenatal death, excluding congenital anomalies (3 RCTs): 0</p> <p>Serious maternal morbidity or death (1 RCT): 0</p> <p>Cervix unfavourable/unchanged after 12–24 hours (3 RCTs): RR 2.44 (95% CI 1.39 to 4.31)</p> <p>Uterine hyperstimulation without FHR changes (5 RCTs): RR 1.54 (95% CI 0.72 to 3.31)</p> <p>Epidural analgesia (3 RCTs): RR 0.72 (95% CI 0.42 to 1.25)</p> <p>Instrumental vaginal birth (9 RCTs): RR 0.98 (95% CI 0.73 to 1.31)</p> <p>Meconium-stained liquor (2 RCTs): RR 0.75 (95% CI 0.40 to 1.41)</p> <p>Apgar score < 7 at 5 minutes (7 RCTs): RR 2.22 (95% CI 0.35 to 13.95)</p> <p>Perinatal death, excluding major congenital anomalies (3 RCTs): 0</p> <p>Maternal nausea (2 RCTs): RR 0.33 (95% CI 0.02 to 7.32)</p> <p>Maternal vomiting (3 RCTs): RR 0.33 (95% CI 0.04 to 3.02)</p> <p>Maternal diarrhoea (2 RCTs): 0</p> <p>Post partum haemorrhage (2 RCTs): RR 1.61 (95% CI 0.62 to 4.19)</p> <p>Women not satisfied (1 RCT): RR 2.32 (95% CI 0.68 to 7.89)</p> <p>Endometritis (2 RCTs): RR 3.00 (95% CI 0.14 to 65.90)</p> <p>Maternal antibiotics (2 RCTs): RR 1.74 (95% CI 0.46 to 6.53)</p> <p>Neonatal infection (3 RCTs): RR 3.00 (95% CI 0.49 to 18.48)</p> <p>Neonatal antibiotics (1 RCT): RR 0.17 (95% CI 0.01 to 3.07)</p>	
Howarth (2001) ¹¹⁸ Country: UK, US, Europe, Australia	Study Type: Systematic review/ meta-analysis Evidence Level: 1++	2566 women near or at term (17 RCTs)	Mixed parity and mixed Bishop score.	Amniotomy and IV oxytocin versus placebo/no treatment: 1 RCT, 184 women Amniotomy and IV oxytocin versus vaginal PGE ₂ : 11 RCTs, 1182	<u>Amniotomy and IV oxytocin versus vaginal PGE₂ (in women with an unfavourable cervix)</u> Vaginal delivery not achieved within 24 hours (1 RCT): RR 0.90 (95% CI 0.46 to 1.75) Caesarean birth (2 RCTs): RR 0.98 (95% CI 0.48 to 2.03) Serious Maternal morbidity or death (1 RCT): 0 Cervix unfavourable/unchanged after 12–24 hours (2 RCTs): RR 0.69 (95% CI 0.20 to 2.35)	University of Pretoria and South African MRC Unit for maternal and Infant Care Strategies

Induction of labour

Bibliographic Information	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
				women	Oxytocin augmentation (1 RCT): RR 0.07 (95% CI 0.00 to 1.12) Uterine hyperstimulation without FHR changes (1 RCT): RR 5.00 (95% CI 0.25 to 99.95)	
				Amniotomy and IV oxytocin versus cervical PGE ₂ : 1 RCT, 60 women	Uterine rupture (1 RCT): RR 3.00 (95% CI 0.13 to 69.70) (previous CS)	
				Amniotomy and IV oxytocin versus oxytocin alone: 2 RCTs, 511 women	Epidural analgesia/opioid analgesia (4 RCTs): RR 1.05 (95% CI 0.81 to 1.35) Instrumental vaginal birth (2 RCTs): RR 1.25 (95% CI 0.54 to 2.90)	
				Amniotomy and IV oxytocin versus amniotomy alone: 2 RCTs, 296 women	Apgar score < 7 at 5 minutes (2 RCTs): RR 7.33 (95% CI 0.39 to 137.73) Neonatal intensive care unit admission (1 RCT): RR 3.00 (95% CI 0.13 to 69.70) Post partum haemorrhage (1 RCT): RR 3.00 (95% CI 0.33 to 27.23) Precipitate labour (1 RCT): RR 3.00 (95% CI 0.13 to 70.83)	
					<u>Amniotomy and IV oxytocin versus vaginal PGE₂ (in women with an unfavourable cervix)</u> No trials	
					<u>Amniotomy and IV oxytocin vs cervical PGE₂ (in women with an unfavourable cervix)</u> No trials	
					<u>Amniotomy and IV oxytocin versus oxytocin alone (in women with an unfavourable cervix)</u> No trials	
					<u>Amniotomy and IV oxytocin versus amniotomy alone (in women with an unfavourable cervix)</u> No trials	
Alfirevic (2006) ¹¹⁹	Study Type: Systematic review/meta-analysis Evidence level: 1++	8606 women (41 RCTs)	Mixed parity, Bishop score from = 4 to = 8.	Oral misoprostol versus placebo: 4 RCTs, 474 women Oral misoprostol versus vaginal dinoprostone: 9 RCTs, 2627 women	<u>Oral misoprostol versus placebo (all women)</u> Long labour: RR 0.16 (95% CI 0.05 to 0.49) Needed oxytocin: RR 0.32 (95% CI 0.24 to 0.43) Caesarean birth: RR 0.62 (95% CI 0.40 to 0.96) <u>Oral misoprostol versus vaginal dinoprostone (all women with intact membrane)</u>	The University of Liverpool

Bibliographic Information	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
				Oral misoprostol versus intracervical prostaglandin E2: 2 RCTs, 391 women	Caesarean birth: RR 0.78, (95% CI 0.66 to 0.94) Uterine hyperstimulation: RR 1.63 (95% CI 1.09 to 2.44), not associated with any fetal adverse events	
				Oral misoprostol versus intravenous oxytocin: 7 RCTs, 1017 women	<u>Oral misoprostol versus intravenous oxytocin (all women)</u> There was a significant increase in meconium-stained liquor in women with ruptured membranes following oral misoprostol: RR 1.72 (95% CI 1.08 to 2.74)	
				Oral misoprostol versus vaginal misoprostol: 16 RCTs, 3645 women	<u>Oral misoprostol versus intracervical misoprostol (all women)</u> No significant difference in maternal and fetal outcomes. <u>Oral misoprostol versus vaginal misoprostol (all women)</u> Uterine hyperstimulation without FH changes: RR 0.37 (95% CI 0.23 to 0.59) Increased need for oxytocin augmentation: RR 1.28 (95% CI 1.11 to 1.48) Meconium-stained liquor: RR 1.27 (95% CI 1.01 to 1.60)	
					<u>Oral versus vaginal misoprostol (in primiparous women with unfavourable cervix)</u> Vaginal delivery not achieved within 24 hours (1 RCT): RR 1.25 (95% CI 1.01 to 1.55) Caesarean birth (2 RCTs): RR 1.89 (95% CI 0.76 to 4.71) Serious neonatal morbidity or perinatal death (2 RCTs): 0 Serious maternal morbidity or death (2 RCTs): 0 Instrumental vaginal birth (1 RCT): RR 0.43 (95% CI 0.06 to 3.28)	
					<u>Oral versus vaginal misoprostol (in multiparous women with unfavourable cervix)</u> Vaginal delivery not achieved within 24 hours (1 RCT): RR 1.41 (95% CI 0.94 to 2.11) Caesarean birth (1 RCT): RR 0.85 (95% CI 0.06 to 12.01) Serious neonatal morbidity or perinatal death (2 RCTs): 0 Serious maternal morbidity or death (2 RCTs): 0 Instrumental vaginal birth (1 RCT): RR 0.85 (95% CI 0.06 to 12.01)	

Induction of labour

Bibliographic Information	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
					<p><u>Oral misoprostol versus vaginal PGE₂ (in women with unfavourable cervix)</u></p> <p>Vaginal delivery not achieved within 24 hours (1 RCT): RR 0.98 (95% CI 0.70 to 1.37)</p>	
Kipikasa (2005) ¹²¹	Study Type: Randomised controlled trial	Total number of women = 52	Women = 41 weeks of gestation, Bishop score = 6.	Oral misoprostol 25 µg versus misoprostol 50 µg	Interval to delivery (days): 3.9 (0.7) versus 2.4 (0.3) (<i>P</i> = 0.0001) Needing one dose misoprostol: 48% versus 77% (<i>P</i> = 0.04) Needing two doses misoprostol: 22% versus 12% (NS) Oxytocin induction: 9% versus 4% (NS) CS: 22% versus 23% (NS) 5 minute Apgar < 6: 0% versus 4% (NS) Meconium-stained fluid: 17% versus 19% (NS) NICU admission: 4% versus 8% (NS)	Source of Funding: None
Country: US	Evidence level: 1+	Oral misoprostol 25 µg <i>n</i> = 23				Computer-generated randomisation, investigators and women blind to group assignment. Tablets (cut into equivalent quarter portions using 100 µg or 200 µg tablets) placed in opaque envelopes.
		Oral misoprostol 50 µg <i>n</i> = 29				
Gherman (2001) ¹²²	Study Type: Randomised controlled trial	Total number of women = 58	Women with mean gestation age of 39 weeks, mixed parity, Bishop score of = 6.	Oral misoprostol 50 µg versus vaginal prostaglandin PGE ₂ 4 mg.	Delivery within 48 hours: 96% versus 77% (<i>P</i> = 0.03) Vaginal birth: 68% versus 80% (NS) CS: 32% versus 20% (NS) Epidural usage: 82% versus 88% (NS) Oxytocin use: 82% versus 47% (<i>P</i> = 0.007) Chorioamnionitis: 4% versus 0% (NS) No of 5 minute Apgar at < 7: 0 versus 0 Meconium passage: 4% versus 10% (NS)	Source of Funding: Nay Bureau of Medicine and Surgery, Washington DC
Country: US	Evidence Level: 1+	Oral misoprostol 50 µg <i>n</i> = 28				Computer-generated randomisation, allocation concealed in sequentially numbered, opaque sealed envelopes prepared by assistant not involved with the trial, care givers blind to allocation, no power calculation.
		Vaginal prostaglandin PGE ₂ 4 mg <i>n</i> = 30				
Paungmora (2004) ¹²⁰	Study Type: Randomised controlled trial	Total number of women = 153	Women at 37–42 weeks of gestation, Bishop score < 6, mixed parity	Oral misoprostol 100 µg versus vaginal misoprostol 100 µg	Induction to delivery interval: 14.3 hours (3.5 to 71.4) versus 15.8 hours (4.6 to 42.6) (NS) Total dose of misoprostol used (ug): 200 (100 to 400) versus 100 (50 to 125) (NS) CS: 44% versus 37% (NS) Analgesia requirement: 84% versus 90% (NS) Tachysystole: 5% versus 17% (<i>P</i> = 0.037) Uterine hyperstimulation: 0 Meconium: 28% versus 13% (<i>P</i> = 0.056) 5 minute Apgar score < 3: 0 versus 0 NICU admission: 1% versus 0% (NS)	Source of Funding: Not stated
Country: Thailand	Evidence level: 1+	Oral misoprostol 100 µg <i>n</i> = 75				Computer-generated randomisation, method of allocation concealment not reported, power calculation.
		Vaginal misoprostol 100 µg <i>n</i> = 76				

Bibliographic Information	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
					Oxytocin augmentation: 52% versus 42% (NS)	
Hofmeyr (2003) ¹²⁴ Country: International	Study Type: Systematic review/ meta-analysis Evidence level: 1++	10 524 women (70 RCTs)	Mixed parity and mixed Bishop score.	Vaginal misoprostol versus placebo: 5 RCTs, 339 women Vaginal misoprostol versus vaginal prostaglandins: 25 RCTs, 3651 women Vaginal misoprostol versus intracervical prostaglandins: 17 RCTs, 2162 women Vaginal misoprostol versus oxytocin: 13 RCTs, 1767 women Misoprostol lower dose regimen versus higher dose: 13 RCTs, 2138 women Misoprostol gel versus tablets: 1 RCT, 467 women	<u>Vaginal misoprostol versus placebo (in women with an unfavourable cervix)</u> Vaginal delivery not achieved within 24 hours (1 RCT): RR 0.36, (95% CI 0.19 to 0.68) Uterine hyperstimulation with FHR changes (3 RCTs): RR 2.31 (95% CI 0.52 to 10.16) Caesarean birth (4 RCTs): RR 0.92 (95% CI 0.57 to 1.47) Cervix unfavourable/unchanged after 12–24 hours (2 RCTs): RR 0.09 (95% CI 0.03 to 0.24) Oxytocin augmentation (2 RCTs): RR 0.38 (95% CI 0.26 to 0.57) Uterine hyperstimulation without FHR changes (3 RCTs): RR 10.11 (95% CI 1.91 to 53.60) Uterine rupture (1 RCT): 0 Instrumental vaginal birth (2 RCTs): RR 1.02 (95% CI 0.50 to 2.12) Meconium-stained liquor (2 RCTs): RR 0.71 (95% CI 0.28 to 1.77) Neonatal intensive care unit admission (2 RCTs): RR 0.41 (95% CI 0.04 to 3.70) Perinatal death (1 RCT): 0 Maternal side effects (1 RCT): RR 2.82(95% CI 0.12 to 66.62) Post partum haemorrhage (2 RCTs): RR 0.91(95% CI 0.13 to 6.37) Serious maternal complication (1 RCT): 0 Maternal death (1 RCT): 0 <u>Vaginal misoprostol versus vaginal prostaglandins (in women with an unfavourable cervix)</u> Vaginal delivery not achieved within 24 hours (13 RCTs): RR 0.80(95% CI 0.73 to 0.87) Uterine hyperstimulation with FHR changes (17 RCTs): RR 2.32 (95% CI 1.62 to 3.32) Caesarean birth (18 RCTs): RR 0.96 (95% CI 0.84 to 1.09) Serous neonatal morbidity or perinatal death (1 RCT): RR 5.98 (95% 0.25 to 145.59) Cervix unfavourable/unchanged after 12–24 hours (1 RCT): RR 0.52 (95% CI 0.27 to 0.98) Oxytocin augmentation (11 RCTs): RR 0.64 (95% CI 0.56 to	South African MRC UNDP/UNFPA/WHO/World Bank University of the Witwatersrand University of For hare, eastern cape South Africa

Induction of labour

Bibliographic Information	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
					<p>0.73) Uterine hyperstimulation without FHR changes (7 RCTs): RR 2.93 (95% CI 2.04 to 4.20) Epidural analgesia (2 RCTs): RR 0.81 (95% CI 0.57 to 1.15) Instrumental vaginal birth (5 RCTs): RR 1.40 (95% CI 0.95 to 2.06) Meconium-stained liquor (7 RCTs): RR 1.45 (95% CI 1.05 to 2.00) Apgar score < 7 at 5 minutes (5 RCTs): RR 1.00 (95% CI 0.61 to 1.63) Neonatal intensive care unit admission (7 RCTs): RR 1.27 (95% CI 0.89 to 1.81) Neonatal encephalopathy (1 RCT): RR 5.98 (95% CI 0.25 to 145.59) Perinatal death (2 RCT): RR 2.85 (95% CI 0.12 to 68.95) Maternal side effects (nausea, vomiting, diarrhoea, (4 RCTs): RR 1.33 (95% CI 0.30 to 5.86) Post partum haemorrhage (3 RCTs): RR 0.56 (95% CI 0.12 to 2.55)</p>	
					<p><u>Vaginal misoprostol versus intracervical prostaglandins (in women with an unfavourable cervix)</u> Vaginal delivery not achieved within 24 hours (5 RCTs): RR 0.68 (95% CI 0.59 to 0.78) Uterine hyperstimulation with FHR changes (14 RCTs): RR 2.19 (95% CI 1.47 to 3.27) Caesarean birth (16 RCTs): RR 1.04 (95% CI 0.88 to 1.23) Cervix unfavourable/unchanged after 12–24 hours (1 RCT): RR 0.68 (95% CI 0.52 to 0.88) Oxytocin augmentation (11 RCTs): RR 0.5 (95% CI 0.51 to 0.62) Uterine hyperstimulation without FHR changes (9 RCTs): RR 1.90 (95% CI 1.44 to 2.49) Uterine rupture (1 RCT): 0 Epidural analgesia (1 RCT): RR 0.71 (95% CI 0.41 to 1.25) Instrumental vaginal birth (8 RCTs): RR 0.87 (95% CI 0.66 to 1.15) Meconium-stained liquor (8 RCTs): RR 1.28 (95% CI 0.96 to 1.69) Apgar score < 7 at 5 minutes (9 RCTs): RR 1.33 (95% CI 0.53 to</p>	

Bibliographic Information	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
					<p>3.32)</p> <p>Neonatal intensive care unit admission (6 RCTs): RR 1.08(95% CI 0.73 to 1.58)</p> <p>Perinatal death (1 RCT): RR 2.85 (95% CI 0.12 to 68.95)</p> <p>Maternal side effects (nausea, vomiting, diarrhoea, 2 RCTs): RR 1.67 (95% CI 0.16 to 17.85)</p> <p>Post partum haemorrhage (2 RCTs): RR 1.62 (95% CI 0.22 to 12.19)</p> <p><u>Vaginal misoprostol versus oxytocin (in women with an unfavourable cervix)</u></p> <p>Vaginal delivery not achieved within 24 hours (2 RCTs): RR 1.00 (95% CI 0.60 to 1.67)</p> <p>Caesarean birth (5 RCTs): RR 0.86(95% CI 0.49 to 1.5)</p> <p>Serious maternal morbidity or death (1 RCT): RR 6.11 (95% CI 0.31 to 119.33)</p> <p>Uterine hyperstimulation without FHR changes (4 RCTs): RR 2.52 (95% CI 1.45 to 4.36)</p> <p>Uterine rupture (1 RCT): RR 6.11 (95% CI 0.31 to 119.33)</p> <p>Instrumental vaginal birth (2 RCTs): RR 0.58 (95% CI 0.05 to 6.17)</p> <p>Meconium-stained liquor (3 RCTs): RR 0.74 (95% CI 0.40 to 1.39)</p> <p>Apgar score < 7 at 5 minutes (3 RCTs): RR 2.13 (95% CI 0.62 to 7.27)</p> <p>Neonatal intensive care unit admission (2 RCTs): RR 1.61 (95% CI 0.81 to 3.21)</p> <p><u>Misoprostol lower dose regimen versus higher dose (in women with an unfavourable cervix)</u></p> <p>Vaginal delivery not achieved within 24 hours (5 RCTs): RR 1.04 (95% CI 0.91 to 1.18)</p> <p>Uterine hyperstimulation with FHR changes (9 RCTs): RR 0.55 (95% CI 0.38 to 0.79)</p> <p>Caesarean birth (9 RCTs): RR 1.00 (95% CI 0.83 to 1.21)</p> <p>Serious maternal morbidity or death (4 RCTs): 0</p> <p>Oxytocin augmentation (5 RCTs): RR 1.30 (95% 1.14 to 1.49)</p> <p>Uterine hyperstimulation without FHR changes (4 RCTs): RR 0.66 (95% CI 0.50 to 0.85)</p>	

Induction of labour

Bibliographic Information	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
					<p>Epidural analgesia (1 RCT): RR 1.04 (95% CI 0.63 to 1.72)</p> <p>Instrumental vaginal birth (4 RCTs): RR 1.01 (95% CI 0.69 to 1.46)</p> <p>Meconium-stained liquor (4 RCTs): RR 1.01(95% CI 0.68 to 1.50)</p> <p>Apgar score < 7 at 5 minutes (5 RCTs): RR 0.78 (95% CI 0.34 to 31.82)</p> <p>Neonatal intensive care unit admission (4 RCTs): RR 0.83 (95% CI 0.62 to 1.10)</p> <p>Maternal side effects (nausea, vomiting, diarrhoea, 4 RCTs): 0.77 (95% CI 0.45 to 1.30)</p> <p>Post partum haemorrhage (1 RCT): RR 1.08 (95% CI 0.27 to 4.25)</p> <p><u>Misoprostol vag gel versus vag tablets (in women with an unfavourable cervix)</u></p> <p>Uterine hyperstimulation with FHR changes (1 RCT): RR 0.49 (95% CI 0.29 to 0.83)</p> <p>Caesarean birth (1 RCT): RR 1.07 (95% CI 0.79 to 1.45)</p> <p>Oxytocin augmentation (1 RCT): RR 1.26 (95% 1.13 to 1.41)</p> <p>Epidural analgesia (1 RCT): RR 1.19 (95% CI 1.03 to 1.38)</p> <p>Instrumental vaginal birth (1 RCT): RR 1.12 (95% CI 0.74 to 1.70)</p> <p>Apgar score < 7 at 5 minutes (1 RCT): RR 1.16 (95% CI 0.56 to 2.38)</p> <p>Neonatal intensive care unit admission (1 RCT): RR 0.76 (95% CI 0.44 to 1.24)</p>	
Muzonzini (2004) ¹³⁴	Study Type: Systematic review/meta-analysis	502 women (3 RCTs)	Mixed parity and mixed Bishop score.	Buccal versus vaginal misoprostol: 1 RCT, 152 women	<p><u>For all women</u></p> <p><u>Sublingual/buccal versus oral misoprostol</u></p> <p>Vaginal delivery not achieved in 24 hours (2 RCTs): RR 0.87 (95% CI 0.68 to 1.11)</p> <p>Uterine hyperstimulation with FHR changes (2 RCTs): RR 1.39 (95% CI 0.28 to 6.96)</p> <p>CS (2 RCTs): RR 0.82 (95% CI 0.57 to 1.19)</p> <p>Cx unfavourable/unchanged after 12–24 hours (2 RCTs): RR 0.20 (95% CI 0.03 to 1.14)</p> <p>Oxytocin augmentation (2 RCTs): RR 0.86 (95% CI 0.68 to 1.07)</p> <p>Epidural analgesia (1 RCT): RR 0.93 (95% CI 0.66 to 1.29)</p> <p>Instrumental vaginal delivery (2 RCT): RR 1.28 (95% CI 0.87to 1.88)</p>	<p>UNDP/UNFPA/WHO/World Bank</p> <p>University of the Witwatersrand</p> <p>University of For hare, eastern cape Sout Africa</p>
Country: UK, US	Evidence level: 1++			Sublingual versus oral misoprostol: 2 RCTs, 350 women		

Bibliographic Information	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
					<p>Apgar score < 7 at 5 minutes (2 RCT): RR 0.99 (95% CI 0.06 to 15.68) NICU admission (2 RCT): RR 0.80 (95% CI 0.44 to 1.47)</p> <p><u>Sublingual/buccal versus vaginal misoprostol</u> Vaginal delivery not achieved in 24 hours (1 RCT): RR 1.22 (95% CI 0.91 to 1.63) Uterine hyperstimulation with FHR changes (1 RCT): RR 1.47 (95% CI 0.80 to 2.71) CS (1 RCT): RR 0.70 (95% CI 0.42 to 1.15) Serious maternal morbidity or death (1 RCT): 0 Cx unfavourable/unchanged after 12–24 hours (1 RCT): RR 3.24 (95% CI 0.13 to 78.38) Oxytocin augmentation (1 RCT): RR 1.06 (95% CI 0.84 to 1.34) Epidural analgesia (1 RCT): RR 1.21 (95% CI 0.57 to 2.56) Instrumental vaginal delivery (1 RCT): RR 0.36 (95% CI 0.10 to 1.28) Apgar score < 7 at 5 minutes (1 RCT): RR 9.73 (95% CI 0.53 to 177.64) NICU admission (1 RCT): RR 1.19 (95% CI 0.54 to 2.64) Serious maternal complications: 0</p> <p><u>For women with an unfavourable cervix</u> No valid outcomes reported</p>	
Crane (2006) ¹³⁵ Country: US, UK, Australia, Greece, Europe	Study Type: Systematic review/ meta-analysis Evidence Level: 1++	2172 women (14 RCTs)	Women at term with unfavourable cervix and intact membranes.	Oral misoprostol versus vaginal PGE ₂ gel (1 RCT) Oral misoprostol versus intracervical PGE ₂ gel (1 RCT) Vaginal misoprostol versus vaginal PGE ₂ gel (4 RCTs) Vaginal misoprostol versus vaginal PGE ₂ controlled release (2 RCTs)	<p><u>Any misoprostol versus PGE₂</u> Risks of tachysystole: RR 1.86 (95% CI 1.01 to 3.43) Hyperstimulation: RR 3.72 (95% CI 2.00 to 6.88) Vaginal delivery within 24 hours: RR 1.14 (95% CI 1.00 to 1.31) Rate of oxytocin use: RR 0.71 (95% CI 0.60 to 0.95) Meconium staining: RR 1.22 (95% CI 0.96 to 1.55) Caesarean birth: RR 0.99 (95% CI 0.83 to 1.17) The use of misoprostol at starting dosages > 25 µg had similar findings to the primary analysis. Lower misoprostol dosing (starting at 25 µg) did not show any significant difference in the outcomes of interest.</p>	Not stated

Induction of labour

Bibliographic Information	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
				Vaginal misoprostol versus vaginal PGE ₂ tablet (1 RCT)		
				Vaginal misoprostol versus vaginal PGE ₂ pessary (1 RCT)		
				Vaginal misoprostol versus intracervical PGE ₂ gel (4 RCTs)		
Kavanagh (2006) ¹³⁸	Study Type: Systematic review/meta-analysis Evidence level: 1++	Total number of women = 168	168 women (1 RCT), at term with normal pregnancy, primip and multip and previous CS.	IM hyaluronidase 20 000 units versus placebo injection.	Caesarean births: 18% versus 49%, RR 0.37 95% CI 0.22 to 0.61) Unchanged cervix after 24 hours: 60% versus 98%, RR 0.62 (95% CI 0.52 to 0.74) Oxytocin augmentation: 10% versus 47%, RR 0.20(95% CI 0.10 to 0.41) Maternal pain: 11% versus 21%, RR 0.51 (95% CI 0.24 to 1.07)	Source of Funding: EPPI Centre, IOE, London UK.
Kelly (2006) ¹³⁹	Study Type: Systematic review/meta-analysis Evidence level: 1++	Total number of women = 66	1 RCT, women with >= 41 weeks GA, favourable cervix.	IM dexamethasone followed by IV oxytocin versus IV oxytocin only.	Caesarean births: 6% versus 15%, RR 0.40 (95% CI 0.08 to 1.92) Uterine hyperstimulation with FHR changes: 0 versus 0 Uterine hyperstimulation without FHR changes: 0 versus 0 Apgar score < 7: 0 versus 0 Maternal fever: 0 versus 0	Source of Funding: EPPI Centre, IOE, London UK
Thomas (2001) ¹⁴⁰	Study Type: Systematic review/meta-analysis Evidence level: 1++	Total number of women = 341	341 women (6 RCTs), requiring induction of labour, Bishop score < 3.	Oestradiol (IV, oral, vaginal or extra-amniotic) versus placebo or prostaglandin or oxytocin	Women with unfavourable cervix Oestrogen versus placebo Caesarean births RR 0.53, (95% CI 0.10 to 2.83) Oestrogen versus PGE ₂ : insufficient data Oestrogen versus oxytocin: insufficient data Oestrogen versus extra-amniotic PGE ₂ : insufficient data	Source of Funding: CESU, RCOG, London UK
Chanrachakul (2000) ¹⁴¹	Study Type: Randomised controlled trial Country: Thailand Evidence level: 1+	Total number of women = 110 6-hourly vaginal glyceryl trinitrate	Women with = 40 weeks of gestation, unfavourable cervix (Bishop score = 6).	6-hourly vaginal glyceryl trinitrate versus 6-hourly PGE ₂ .	5 minute Apgar score < 7: 0% versus 2% (NS) Achieving a median Bishop score > 6 within 24 hours: 39% vs 59% (P = 0.06) Duration from start of medication to delivery:	

Bibliographic Information	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
		<i>n</i> = 54			26.2 (6.4) hrs vs 21.8 (7.7) hrs (<i>P</i> < 0.01) Need for oxytocin: 78% versus 43% (<i>P</i> < 0.001) Tachysystole: 0 % versus 9% (<i>P</i> = 0.02) Side effects headaches: 10% vs 0% (<i>P</i> = 0.02) Palpitation: 7% vs 0% (<i>P</i> = 0.04) Vaginal birth: 35% versus 36% (NS) CS: 35% versus 36% (NS) Admission to NICU: 0% versus 2% (NS)	
Osman (2006) ¹⁴³ Country: UK	Study Type: Randomised controlled trial Evidence Level: 1+	Total number of women = 398 Nitrous oxide donor isosorbide mononitrate (IMN) <i>n</i> = 199 Prostaglandins E2 gel (PGE ₂) <i>n</i> = 199	Primigravid women, singleton, > 38 weeks GA, Bishop score < 6.	IMN versus PGE ₂ gel	Mean time from treatment to delivery (hours): 39.7 (12) versus 26.9 (12.5) (<i>P</i> < 0.0001) Changes in Bishop score at 24 hours: 1.35 (1.15) versus 2.79 (2.00) Mean difference 1.45, 95% CI 0.95 to 1.95) Abnormal fetal heart rates: 0% versus 6.5% (<i>P</i> = 0.0002) Vaginal bleeding: 0% versus 0.5% (NS) Nausea: 20% versus 11% (<i>P</i> = 0.024) Hot flushes: 22% versus 11% (<i>P</i> = 0.004) Headaches: 88% versus 10% (<i>P</i> = 0.0001) Faintness: 5% versus 1% (<i>P</i> = 0.04) Drowsiness: 8% versus 6% (NS) Abdominal/pelvic pain visual analogue scale > 7: 0% versus 15% (<i>P</i> < 0.0001) Maternal satisfaction (VAS 1–10, 10 very satisfied): 7.0 (2.7) versus 5.8(3.1) (<i>P</i> < 0.0001) Preference for treatment as an outpatient: 55% versus 17% (<i>P</i> < 0.0001) Preference for outpatient treatment if a safe, nonpainful method was available: 83% versus 69% (<i>P</i> = 0.0006)	Source of Funding: Sir Jules Thorn Charitable Trust Computer generated randomisation, allocation in sequentially numbered opaque envelopes blind to investigators and patients, power calculation.

5.2 Non-pharmacological methods

Bibliographic details	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
Boulvain (2005) ¹⁴⁶ Country: US, UK, Belgium, Canada, India, Thailand, China	Study Type: Systematic review/ meta-analysis Evidence level: 1++	27 097 women (22 RCTs)	Women from 37- = 40 weeks GA Bishop score (from closed cervix to >/=6) Mixed parity Mixed case load	<u>Membrane sweeping versus no treatment (19 RCTs)</u> Women at 37–40 weeks GA (13 RCTs) =40 weeks GA (6 RCTs) <u>Membrane sweeping versus prostaglandins (3 RCTs)</u> =40 weeks GA <u>Membrane sweeping versus oxytocin (1 RCT)</u> Sweeping frequency Weekly sweeping (7 RCTs) Sweeping every 3 days (1 RCT) Daily sweeping (2 RCTs) Sweeping frequency not reported (12 RCTs)	<u>Membrane sweeping versus no treatment (for all women)</u> Formal induction of labour: (12 RCTs): RR 0.60 (95% CI 0.51 to 0.71) CS (18 RCTs): RR 0.90 (95% CI 0.70 to 1.15) Reduced frequency of pregnancy beyond 41 weeks (6 RCTs): RR 0.59 (95% CI 0.46 to 0.74) Reduced frequency of pregnancy beyond 42 weeks (6 RCTs): RR 0.28 (95% CI 0.15 to 0.50) NNT to avoid on formal induction of labour: 8 Perinatal death: *2/401 versus **2/399 RR 1.0 (95% CI 0.20 to 4.88) * congenital heart defect, stillbirth: meconium-stained liquor ** congenital heart defect, double nuchal cord Serious maternal death (6 RCTs): 0 Oxytocin augmentation (3RCTs): RR 0.96 (95% CI 0.80 to 1.14) Epidural usage (6 RCTs): RR 1.08 (95% CI 0.94 to 1.23) Instrumental delivery (14 RCTs): RR 1.15 95% (CI 0.94 to 1.42) PPH(3 RCTs): RR 0.31 (95% CI 0.11 to 0.89) Prelabour rupture of membranes (10 RCTs): RR 1.14 (95% CI 0.89 to 1.45) Maternal infection/fever (11 RCTs): RR 1.05 (95% CI 0.68 to 1.65) Neonatal infection (6 RCTs): RR 0.92 (95% CI 0.0 to 2.82) Meconium-stained liquor (2 RCTs) : RR 0.67 (95% CI 0.33 to 1.35) Apgar score < 7 at 5 minutes (8 RCTs): RR 1.13 (95% CI 0.53 to 2.43) Admission to NICU (7 RCTs): RR 0.92 (95% CI 0.52 to 1.63) Pain and discomfort reported (2RCTs): RR 2.83 (95% CI 2.03 to 3.96) Sig higher median score (pain index and visual analogue scale) 70% reported that membrane sweeping associated with sig discomfort and pain Vaginal bleeding (3 RCTs): RR 1.75, (95% CI 1.08 to 2.83) <u>Membrane sweeping versus prostaglandins</u> CS 3 RCTs): RR 0.70 (95% CI 0.44 to 1.10) Oxytocin augmentation (1 RCT): RR 0.83 (95% CI 0.50 to 1.36) Instrumental vaginal birth (3 RCTs): RR 1.67 (95% CI 0.81 to 3.46)	Source of Funding: University of Geneva

Bibliographic details	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
					<p>Meconium-stained liquor (1 RCT): RR 1.37 (95% CI 0.61 to 3.10) Apgar score < 7 at 5 minutes (3 RCTs): RR 0.83 (95% CI 0.14 to 4.92) NICU admission (3 RCTs): RR 0.37 (95% CI 0.12 to 1.17) PPH (1 RCT): 0 Not delivered before 42 weeks (2 RCTs): RR 0.50 (95% CI 0.25 to 1.02)</p>	
					<p><u>Membrane sweeping versus oxytocin</u> CS (1 RCT): RR 0.69 (95% CI 0.12 to 3.85) Formal induction of labour (1 RCT): RR 0.51 (95% CI 0.05 to 5.42)</p>	
					<p><u>In women with an unfavourable cervix</u> <u>Sweeping versus no treatment</u></p> <p>Requiring formal induction of labour (3 RCTs): RR 0.51 (95% CI 0.37 to 0.71) Caesarean births (3 RCTs): RR 0.98 (95% CI 0.49 to 1.95) Instrumental vaginal delivery (2 RCTs): RR 0.87 (95% CI 0.33 to 2.24) 5 minute Apgar score < 7 (1 RCT): RR 0.97 (95% CI 0.06 to 4.85) Neonatal intensive care unit admission (1 RCT): RR 0.97 (95% CI 0.15 to 6.47) Serious maternal or neonatal morbidity/perinatal death (1 RCT): 0 Maternal infection (1 RCT): RR 0.11 (95% CI 0.01 to 1.93) Prelabour rupture of membranes: (1 RCT): RR 2.00 (95% CI 0.39 to 10.22) Epidural analgesia (1 RCT): RR 0.70 (95% CI 0.42 to 1.18)</p>	
					<p><u>Membrane sweeping versus vaginal prostaglandins</u> Not delivered before 42 weeks (2 RCTs): RR 0.50 (95% CI 0.25 to 1.02) Caesarean births (2 RCTs): RR 0.67 (95% CI 0.41 to 1.08) Instrumental vaginal delivery (2 RCTs): RR 1.10 (95% CI 0.48 to 2.50) 5 minute Apgar score < 7 (1 RCT): RR 0.33 (95% CI 0.01 to 7.91) Neonatal intensive care unit admission (2 RCTs): RR 0.38 (95% CI 0.10 to 1.38) Requiring 'formal' induction of labour (1 RCT): RR 0.85 (95% CI 0.44 to 1.62) Prelabour rupture of membranes (1 RCT): RR 0.57 (95% CI 0.18 to 1.78)</p>	

Induction of labour

Bibliographic details	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
					<p><u>Membrane sweeping versus oxytocin</u></p> <p>Requiring 'formal' induction of labour (1 RCT): RR 0.51 (95% CI 0.05 to 5.42)</p> <p>Caesarean birth (1 RCT): RR 0.69 (95% CI 0.12 to 3.85)</p>	
Allot (1993) ¹⁵⁶	Study Type: Randomised controlled trial	195 women	Low-risk pregnancy beyond 40 weeks (confirmed by US)	Membrane sweeping (n = 99) versus vaginal exam (VE) (n = 96)	Not delivered within 48 hours: 47% versus 76%, RR 0.62 (95% CI 0.49 to 0.79)	Computer randomisation: assignment in sealed envelopes, power calculation
Country: UK			Primigravida		Formal induction of labour required: 8% versus 19% (P = 0.035)	
Study included in SR ¹⁴⁶	Evidence Level: 1+		Membrane sweeping: 43% VE: 46%	Frequency of sweeping: not reported	Caesarean section: 5.3% versus 4%, RR 0.78 (95% CI 0.21 to 2.80)	Bishop's score ≤ 6: low
			Bishop's score (BS) ≤ 6		Instrumental vaginal delivery: 11% versus 12%, RR 0.89 (95% CI 0.41 to 1.92)	Bishop's score: ≥ 7: high
			Membrane sweeping: 44% VE: 44%		Epidural in labour: 19% versus 21%, RR 0.92 (95% CI 0.53 to 1.62)	Women's views on sweeping: Not reported
			≥ 7		Maternal pyrexia: 1% versus 1%, RR 0.97 (95% CI 0.06 to 15.28)	
			Membrane sweeping: 56% VE: 56%		Apgar score < 7 at 5 minutes: 0% versus 0%	Funding: not stated
			Exclusion: closed cervix		Serious neonatal infection: 0% versus 1%	
					Cumulative proportions of spontaneous labour within 3 days:	
					All women: 65% versus 31% (P = 0.0001)	
					Primig: 61% versus 31% (P = 0.0021)	
					Multip: 68% versus 31% (P = 0.0003)	
					Low BS: 71% versus 21% (P = 0.0001)	
					High BS: 60% versus 39% (P = 0.04)	
					Primig + low BS: 69% versus 13% (P = 0.0002)	
					Primig + high BS: 56% versus 41% (P = 0.42)	
					Multip + low BS: 73% versus 26% (P = 0.0023)	
					Multip + high BS: 63% versus 36% (P = 0.03)	
El-Torkey (1992) ¹⁵⁷	Study Type: Randomised controlled trial	65 women	Women with pregnancy between 41–42 weeks GA	Membrane sweeping (n = 33) versus no sweeping (n = 32)	Spontaneous labour (self-admission to hospital with regular contractions occurring ≥ twice in 10 minutes): 76% versus 37%, OR 4.65 (95% CI 1.85 to 12.31)	Randomisation by random permuted blocks, codes placed in opaque sealed envelopes, power calculation
Country: UK			Primigravida		In sweeping group:	
Study included in SR ¹⁴⁶	Evidence Level: 1+		Membrane sweeping: 51% Control: 44%	6 women in sweeping group required cervical massage due to unfavourable cervix.	89% had spontaneous labour (44% within 24 hours, 72% within 48 hours and 84% within 72 hours) versus 17% of women with unfavourable cervix had spontaneous labour	Funding: not stated
			Cervix > 4 cm at first exam: Sweeping 49% No sweeping 16% (P = 0.005)	Frequency of sweeping not reported.	Cervical dilation ≥ 4 cm at first exam: 48% versus 16%, OR 4.39 (95% CI 1.56 to 12.32)	Trial stopped early because of high % of women achieving spontaneous labour.
					Pyrexia in labour/puerperium, requiring antibiotics: 0% versus 12%, OR 0.12 (95% CI 0.02 to 0.88)	

Bibliographic details	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
					Analgesia use/Modes of delivery/Neonatal outcomes: Similar in the two groups Serous infection: None Perinatal death: None Women's views on sweeping: Not reported	
Boulvain (1998) ¹⁵⁴ Country: Canada Study included in SR ¹⁴⁶	Study Type: Randomised controlled trial Evidence Level: 1+	200 women	Women with non-urgent medical indications for induction of labour (85% post-term: ≥ 287 days GA; 3.5% hypertension, 2.5% diabetes, 1.5% fetal growth restriction, 6.5% others: ≥ 266 days GA) GA confirmed by last menstrual period and US Nulliparous: Membrane sweeping: 58% Control: 50% Bishop's score: < 6: Membrane sweeping: 46% Control: 51%	Membrane sweeping (n = 99) versus vaginal exam (VE) (n = 99) Frequency of sweeping not reported.	Duration of labour (hour): 8.7 versus 8.8 (NS) Formal induction of labour required: 49% versus 59%, RR 0.83 (95% CI 0.64 to 1.07) Epidural use: 75 versus 69 (NS) Caesarean section: 12 versus 12 (NS) Forceps/vacuum: 36 versus 27 (NS) Maternal pyrexia: 8 versus 8 (NS) Apgar score < 7 at 5 minutes: 3 versus 0 (NS) Neonatal infection: 1 versus 1 (NS) Admission to NICU: 6 versus 6 (NS) Pain (VAS) during VE: 2.4 versus 1.5 (P = 0.001) Bleeding before onset of labour: 45% versus 26% (P = 0.02) Recommended sweeping to friends: 87% Advantages more superior to disadvantages: 77% Sweeping as useless: 9% Unpleasant: 31% Painful: 22%	Computer randomisation, in blocks of six and eight, stratified by hospital Assignment in opaque sealed envelopes Power calculation Included pregnancies with medical complications Funding: Health Canada, Astra Pharma, MRC
Magann (1998) ¹⁵³ Country: US	Study Type: Randomised controlled trial Evidence level: 1+	Total number of women = 105 Daily membrane sweeping n = 35 Daily PGE ₂ gel n = 35 Daily cervical examination n = 35	Women at 41 weeks of gestation, mean Bishop score < 3.	Daily membrane sweeping versus daily PGE ₂ gel versus daily cervical examination.	Sweeping vs PGE ₂ vs control Induction at 42 weeks: 17% versus 20% versus 63% (P < 0.0001) Duration of labour: 10.1 (6.1) hr versus 14.2 (6.0) hr versus 20 (7.0) hr (P < 0.05) Bishop score on admission to labour ward: versus control (P < 0.001) (no data) spontaneous vaginal birth: 26 versus 24 versus 25 (NS) instrumental birth: 4 versus 3 versus 5 (NS) CS: 5 versus 8 versus 5 (NS) 5 minute Apgar score at < 7:0 versus 1 versus 1 (NS) Admission to well-baby nursery: 33 versus 32 versus 35 (NS)	Source of Funding: Vicksburg Hospital Medical Foundation Randomisation using random number table, allocation in a series of sealed opaque envelopes, power calculation.
Magann (1999) ¹⁵²	Study Type:	Total number of	Women of mixed parity at	Daily membrane sweeping	Bishop score on admission to labour ward: 8.56 (2.50) versus 6.63	Source of Funding: Vicksburg

Induction of labour

Bibliographic details	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
Country: US	Randomised controlled trial Evidence level: 1+	women = 182 Daily membrane sweeping <i>n</i> = 91 Daily placement of a dinoprostol vaginal suppository <i>n</i> = 91	41 weeks of gestation, mean Bishop score < 3.	versus daily placement of a dinoprostol vaginal suppository.	(2.55) (<i>P</i> < 0.001) Mean admission to delivery interval (hr) : 10.8 (6.9) versus 13.1 (6.7) (<i>P</i> = 0.01) Spontaneous vaginal birth: 74% versus 65% (NS) Instrumental birth: 8% versus 8% (NS) CS: 19% versus 27% (NS) 5 minute Apgar score < 7: 0 versus 0 NICU admission: 1 versus 5 (NS) Induction at 42 weeks: 9% versus 14% (<i>P</i> = 0.041)	Hospital Medical Foundation Randomisation using table of random numbers allocation in sealed opaque envelopes, power calculation.
Wiriyasirivaj (1996) ¹⁴⁹ Country: Thailand	Study Type: Randomised controlled trial Evidence level: 1+	Total number of women = 120 Weekly membrane sweeping <i>n</i> = 61 Weekly gentle pelvic examination <i>n</i> = 59	Women at 38 weeks of gestation mean Bishop score < 3	Weekly membrane sweeping versus weekly gentle pelvic examination.	Delivery within 7 days of first pelvic exam: 41% versus 20% (<i>P</i> = 0.014) Oxytocin use: 44% versus 44% (NS) Spontaneous vaginal birth: 74% versus 76% (NS) Instrumental vaginal birth: 16% versus 19% (NS) CS: 10% versus 5% (NS) 5 minute Apgar < 7: 9.9 (0.2) versus 9.9 (0.1) (NS) Postpartum fever: 2% versus 0% (NS) Postpartum haem: 3% versus 3% (NS)	Source of Funding: Not stated Randomisation using table of random numbers, allocation kept in sealed black opaque envelope, no pwer calculation.
Magann (1998) ¹⁵⁰ Country: US	Study Type: Randomised controlled trial Evidence level: 1+	Total number of women = 65 Membrane sweeping every 3 days <i>n</i> = 33 Gentle vaginal examination every 3 days <i>n</i> = 32	Women of mixed parity at 39 weeks of gestation, median Bishop score < 3.	Membrane sweeping every 3 days versus gentle vaginal examination every 3 days.	Bishop score at delivery ≥ 8: 19 versus 6 (<i>P</i> = 0.0002) Induction at 42 weeks: 0 versus 18 (<i>P</i> < 0.0001) Vaginal birth: 29 versus 27 (NS) CS: 4 versus versus 5 (NS) NICU: 2 versus 2 (NS)	Source of Funding: Not stated Randomisation using random number table, allocation in consecutive series of sealed apaque envelopes, power calculation.
Berghella (1996) ¹⁴⁸ Country: US	Study Type: Randomised controlled trial Evidence level: 1+	Total number of women = 142 Weekly membrane sweeping <i>n</i> = 73	Women = 38 weeks of gestation, mean Bishop score < 4.	Weekly membrane sweeping versus weekly gentle cervical examination.	Days to delivery: 8.2 (6.3) versus 12.1(7.1) (<i>P</i> < 0.002) Spontaneous vaginal birth: 90% versus 86% (NS) Instrumental birth: 10% versus 10% (NS) CS: 0% versus 4% (NS) Days to delivery in women with Bishop score ≤ 3: 8.6 (6.4) (<i>n</i> = 39) versus 12.5 (6.8) (<i>P</i> < 0.02) (<i>n</i> = 44) Days to delivery in women with Bishop score > 3: 6.5 (5.4) (<i>n</i> = 34)	Source of Funding: not stated Computer-generated randomisation Allocation in sealed opaque envelopes Power calculation

Bibliographic details	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
		Weekly gentle cervical examination <i>n</i> = 69			versus 11.5 (8.2) (NS) (<i>n</i> = 25) Days to delivery in nulliparous women: 7.8 (6.0) (<i>n</i> = 35) versus 12.9 (6.6) (<i>P</i> < 0.009) (<i>n</i> = 43) Days to delivery in multiparous women: 7.2 (5.9) (<i>n</i> = 38) versus 11.0 (7.9) (NS) (26)	
Cammu (1998) ¹⁴⁷ Country: Belgium	Study Type: Randomised controlled trial Evidence level: 1+	Total number of women = 278 Weekly membrane sweeping <i>n</i> = 140 Normal digital examination <i>n</i> = 139	Nulliparous women with uncomplicated pregnancies, 39 completed weeks of gestation, mean Bishop score < 4.	Weekly membrane sweeping versus normal digital examination.	Randomisation to delivery interval: 9.4 days versus 10.6 days (NS) Spontaneous labour: 51% versus 42% (NS) Induced labour: 11% versus 26%, OR 0.34 (95% CI 0.18 to 0.66) Epidural: 38% versus 38% (NS) Instrumental birth: 16% versus 13% (NS) CS: 4% versus 6% (NS) 5 minute Apgar score: 3 versus 7 (NS)	Source of Funding: Not stated Computer-generated randomisation, allocation in sealed numbered envelopes, opened after entry to trial, power calculation.
Dare (2002) ¹⁵⁵ Country: Nigeria	Study Type: Randomised controlled trial Evidence level: 1+	Total number of women = 137 Membrane sweeping <i>n</i> = 69 Control (gentle cervical examination) <i>n</i> = 68	Women at 38 weeks of gestation, mean Bishop score > 4.	Membrane sweeping versus gentle cervical examination.	Mean time to delivery (days): 4.8 (0.9) versus 12.1 (1.4) (<i>P</i> < 0.001) Spontaneous vaginal birth: 68% versus 65% (NS) Instrumental vaginal birth: 23% versus 16% (NS) CS: 9% versus 19% (<i>P</i> = 0.09) CS due to acute fetal distress: 2 versus 8 (<i>P</i> = 0.055) CS due to non-progress of labour: 4 versus 5 (NS) Maternal discomfort during vaginal exam: 66% versus 21% (<i>P</i> < 0.001) Prelabour rupture of membranes: 11% versus 9% (NS) Intrapartum chorioamnionitis: 2 versus 1 (NS) 5 minute Apgar < 7: 2 versus 1 (NS) NICU admission: 13% versus 16% (NS) Vaginal bleeding: 3% reported in sweeping group	Source of Funding: Not stated Computer-generated randomisation, allocation in numbered opaque sealed envelope drawn in consecutive order, power calculation.
de ME (2006) ¹⁵¹ Country: The Netherlands	Study Type: Randomised Controlled Trial Evidence Level: 1+	Total number of patients = 742 Sweeping <i>n</i> = 375 Control <i>n</i> = 367	Low-risk pregnant women at 41 weeks GA Nulliparity: 53% Bishop scores: < 6: 38% ≥ 6: 11%	Membrane sweeping every 48 hours versus routine monitoring	<u>Outcomes at 5 Days:</u> Post term pregnancy in nulliparous and multiparous women: 23% versus 41% (RR 0.57, 95% CI 0.46 to 0.71) Spontaneous onset of labour >42 weeks: 9% versus 14% (RR 0.59, 95% CI 0.39 to 0.89) Induction of labour in parous women: 15% versus 27% (RR 0.57, 95% CI 0.37 to 0.86) Induction of labour in nulliparous women: 29% versus 31% (RR 0.92, 95% CI 0.68 to 1.25) Mode of delivery: spontaneous: 76% versus 76% (NS) Mode of delivery: instrumental: 15% versus 14% (NS)	Source of Funding: ZONMw Block randomisation, allocation within consecutively numbered opaque sealed envelopes Power calculation

Induction of labour

Bibliographic details	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
					Mode of delivery: CS: 10% versus 10% (NS) Fever during labour: = 38° C: 7/375 versus 3/367 Analgesia use: epidural: 5% versus 4% (NS) Analgesia: Pethidine: 13% versus 12% (NS)	
Smith (2004) ¹⁵⁹	Study Type: Systematic review/meta-analysis Evidence level: 1++	Total number of women = 56	1 RCT, 56 women with uncomplicated singleton pregnancies, Bishop score < 5, mixed parity.	Acupuncture every two days versus no acupuncture.	No outcomes provided on these women.	Source of Funding: University of Adelaide, Australia 20% drop out rate, imbalance in post randomisation exclusions (5 in acupuncture group, 8 in control group). Overall, no meaningful outcomes for interpretation
Harper (2006) ¹⁶⁰	Study Type: Randomised controlled trial Evidence level: 1+	Total number of women = 56	Nulliparous women >=39 weeks GA with singleton pregnancy, median Bishop score 4.	Outpatient acupuncture treatment + usual medical care versus usual medical care (not specified).	Time to delivery (hours) from enrolment: 124 (SD 86.7) versus 145 (SD 82.7) (NS) Spontaneous labour: 70% versus 50%, OR 2.33 (95% CI 0.78 to 6.98) Caesarean births: 17% versus 39%. OR 3.13 (95% CI 0.99 to 10.8) 5 minute Apgar score: NS Admission to NICU: NS	Source of Funding: Bowes Cefalo Young Researcher Award Computer generated randomisation in equal blocks of two and four. Group assignment in numbered sealed envelopes opened by principle investigator, care providers and patients not blind.
Smith (2003) ¹⁶²	Study Type: Systematic review/meta-analysis Evidence level: 1++	Total number of women = 133	133 women with GA 36–42 weeks (2 RCTs) 40 women with cervical score ≤ 4 cm and prelabour rupture of membranes (1 RCT) (in German) No information from the other RCT (in French)	Homeopathy (herb Caulophyllum) versus placebo.	Vaginal delivery within 24 hours: 1 versus 0, RR 5.0, (95% CI 0.26 to 98.00) Caesarean births: 2 versus 0, RR 5.0 (95% CI 0.26 to 98.00) Uterine hyperstimulation: No data Serous maternal morbidity (postpartum haem, admission to intensive care, septicaemia): No data Serious neonatal morbidity (Apgar score, NICU admission): No data Oxytocin augmentation: 9 versus 9, RR 1.0 (95% CI 0.50 to 1.98) Instrumental delivery: RR 1.0 (95% CI 0.54 to 1.86) Vaginal delivery within 24 hours: RR 0.33 (95% CI 0.01 to 7.72) Report of difficult labour (1 RCT): 6 versus 16, RR 0.28, (95% CI 0.12 to 0.66) Caesarean births: 2 versus 0, RR 5.0, (95% CI 0.26 to 98.00)	Source of Funding: University of Adelaide, Australia

Bibliographic details	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
					<p>Uterine hyperstimulation: No data</p> <p>Serious maternal morbidity (postpartum haem, admission to intensive care, septicaemia): No data</p> <p>Serious neonatal morbidity (Apgar score, NICU admission): No data</p> <p>Oxytocin augmentation: 9 versus 9, RR 1.0 (95% CI 0.50 to 1.98)</p> <p>Instrumental delivery: RR 1.0 (95% CI 0.54 to 1.86)</p> <p>Mean length of labour (1RCT): 5.1 hours versus 8.48 hours ($P < 0.001$)</p> <p>Report of difficult labour (1RCT): 11.3% versus 40%, RR 0.28 (95% CI 0.12 to 0.66)</p>	
Kelly (2001) ¹⁶³	<p>Study Type: Systematic review/meta-analysis</p> <p>Evidence level: 1++</p>	Total number of women = 103	<p>1 quasi-RCT, 103 women with singleton pregnancy requiring induction of labour, intact membranes, Bishop score < 4.</p> <p>Parity unknown</p>	Castor oil (60 ml) diluted in orange juice versus no treatment.	<p>All women:</p> <p>Caesarean birth: 19% versus 8.3%, RR 2.31 (95% CI 0.77 to 6.87)</p> <p>Meconium-stained liquor: 9.6% versus 12.5% , RR 0.77, (95% CI 0.25 to 2.36)</p> <p>5 minute Apgar score < 7: no data</p> <p>Nausea with ingestion of castor oil: RR 97.08 (95% CI 6.16 to 1530.41)</p>	Source of Funding: no funding
Kavanagh (2001) ¹⁶⁵	<p>Study Type: Systematic review/meta-analysis</p> <p>Evidence Level: 1++</p>	Total number of women = 28	<p>1 RCT, 56 women with > 39 weeks of gestation</p> <p>Bishop score and parity unknown (paper in Dutch).</p>	Sexual intercourse for 3 consecutive nights with vaginal sperm deposit versus no sexual intercourse.	<p>5 minute Apgar score < 7: 0% versus 0%</p> <p>Mean change in Bishop score: 1.0 versus 0.5 (p,0.05)</p> <p>Women delivered within 3 days of intervention: 46% versus 47%, RR 0.99 (95% CI 0.45 to 2.20)</p>	Source of Funding: CESU, RCOG, London UK EPPI-Centre, IOE, London UK
Kavanagh (2005) ¹⁶⁹	<p>Study Type: Systematic review/meta-analysis</p> <p>Evidence level: 1++</p>	Total number of women = 719	6 RCTs, 719 pregnant women (low and high risk), due for 3rd trimester induction of labour carrying a viable fetus, Bishop score 5–7, mixed parity.	Breast stimulation versus no breast stimulation or oxytocin infusion.	<p>In all women:</p> <p>Caesarean births (1 RCT): 9% versus 10%, RR 0.90 (95% CI 0.38 to 2.12)</p> <p>Achieving labour within 72 hours (4 RCTs): 63% vs 94% (RR 5.79, 95% CI 3.41 to 9.81)</p> <p>Perinatal death (1 RCT): 1.8% versus 0%, RR 8.17 (95% CI 0.45 to 147.76)</p> <p>Meconium staining (2 RCTs): 25.6% versus 30%, RR 0.85 (95% CI 0.56 to 1.28)</p> <p>Post-partum haemorrhage (2 RCTs): 0.7% versus 6%, RR 0.16 (95% CI 0.03 to 0.87)</p> <p>Women's satisfaction: NS</p>	Source of Funding: CESU, RCOG, London UK; EPPI-Centre, IOE, London.

5.3 Surgical methods

Bibliographic details	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
Bricker (2005) ¹⁷⁰	Study Type: Systematic review/ meta-analysis Evidence Level: 1++	310 women 2 RCTs (1 Quasi-RCT)	Women with complicated and uncomplicated pregnancies, requiring induction of labour, Bishop score ≤ 4 to ≥ 6.	Amniotomy versus no intervention versus oxytocin versus vaginal prostaglandin	<p><u>Amniotomy versus no intervention (1 quasi-RCT)</u> CS: 40% versus 0%, RR 9.95 (95% CI 0.55 to 147.96)</p> <p><u>Amniotomy versus oxytocin (1 quasi-RCT)</u> CS: 40% versus 30%, RR 1.33 (95% CI 0.40 to 4.49)</p> <p><u>Amniotomy versus vaginal prostaglandin (1 RCT)</u> CS: 46% versus 39% (NS) Perinatal death: 0 versus 0 Increase in oxytocin augmentation: 44% versus 15%, RR 2.85 (95% CI 1.82 to 4.46) Primiparae: 51% versus 22%, RR 2.33 (95% CI 1.33 to 4.10) Multiparae: 39% versus 11%, RR 3.63 (95% CI 1.77 to 7.41) Uterine hyperstimulation with FHR changes: 0 versus 0 Epidural usage: NS Increase in intrapartum maternal pyrexia: NS Meconium-stained liquor: NS Post-partum haemorrhage: NS</p> <p><u>Amniotomy versus no treatment (in women with unfavourable cervix)</u> Caesarean births (1 quasi-RCT): RR 9.00 (95% CI 0.55 to 147.95)</p> <p><u>Amniotomy versus oxytocin (in women with unfavourable cervix)</u> Caesarean births (1 quasi-RCT): RR 1.33 (95% CI 0.40 to 4.49)</p>	Funding: University of Liverpool, UK
Boulvain (2001) ¹⁷¹	Study Type: Systematic review/ meta-analysis Evidence Level: 1++	5385 women (45 RCTs)	Women needing induction of labour, mixed parity and BS.	Any mechanical method versus placebo/no treatment Laminaria tent versus placebo/no treatment Balloon catheter versus no treatment	<p><u>Any mechanical method versus placebo/no treatment</u> Vaginal birth not achieved in 24 hours (1 RCT, 48 women): 69% versus 77%, RR 0.90 (95% CI 0.64 to 1.26)</p> <p>Caesarean section (6 RCTs, 416 women): 34% versus 34, RR 1.00 (95% CI 0.76 to 1.30)</p> <p>Fetal heart rate changes: no report Severe maternal and neonatal morbidity or infection: no instances</p>	Source of Funding: University of Geneva International populations

Bibliographic details	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
				Any mechanical method versus intravaginal prostaglandins	<u>Laminaria tent versus placebo/no treatment</u> Caesarean birth (5 RCTs): RR 0.98 (95% CI 0.74 to 1.30)	
				Laminaria tent versus any prostaglandins	<u>Balloon catheter versus no treatment</u> Caesarean births (1 RCT): RR 1.17 (95% CI 0.47 to 2.92)	
				Balloon catheter versus prostaglandins	<u>Any mechanical method versus intravaginal prostaglandins</u> Vaginal birth not achieved in 24 hours (1 RCT): 68% versus 40%, RR 1.70 (95% CI 1.15 to 2.51)	
				Any mechanical method versus intracervical prostaglandins	Hyperstimulation with FHR changes (1 RCT): 0% versus 1%, RR 0.21 (95% CI 0.04 to 1.20) Caesarean births(12 RCTs): 28% versus 25%, RR 1.13 (95% CI 0.96 to 1.32)	
				Laminaria tent + prostaglandins vs prostaglandins alone	Instrumental birth (6 RCTs): 14% versus 14%, RR 1.01 (95% CI 0.70 to 1.47) Serious maternal and neonatal morbidity was infrequent	
				Balloon catheter + prostaglandins versus prostaglandins alone	<u>Laminaria tent versus any prostaglandins</u> Caesarean births (9 RCTs): RR 1.15 (95% CI 0.95 to 1.39) Less hyperstimulation with FHR changes: RR 0.13 (95% CI 0.04 to 0.48)	
				Any mechanical method versus misoprostol	Serious maternal and neonatal morbidity was infrequent	
				Any mechanical method versus Oxytocin	<u>Balloon catheter versus prostaglandins</u> Not achieved vaginal birth within 24 hours: RR 1.51 (95% CI 1.16 to 1.98) Caesarean birth (11 RCTs): RR 1.09 (95% CI 0.89 to 1.33) Less hyperstimulation with FHR changes (1 RCT): RR 0.08 (95% CI 0.01 to 0.55)	
				Laminaria tent versus oxytocin	Hyperstimulation without FHR changes: RR 2.47 (95% CI 0.91 to 6.70) Serious maternal and neonatal morbidity was infrequent.	
				Laminaria tent + oxytocin versus oxytocin alone	<u>Any mechanical method versus intracervical prostaglandins</u>	
				Balloon catheter versus oxytocin	Vaginal birth not achieved in 24 hours (1 RCT): 68% versus 40%, RR 1.70 (95% CI 1.15 to 2.51)	
				Laminaria vs extra-amniotic infusion	Hyperstimulation with FHR changes (1 RCT): 0% versus 1%, RR 0.21 (95% CI 0.04 to 1.20)	

Induction of labour

Bibliographic details	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
				Extra-amniotic infusion versus any prostaglandins	<p>Caesarean births (12 RCTs): 28% versus 5%, RR 1.13 (95% CI 0.96 to 1.32)</p> <p>Instrumental birth (6 RCTs): 14% versus 14%, RR 1.01 (95% CI 0.70 to 1.47)</p> <p>Serious maternal and neonatal morbidity was infrequent.</p> <p><u>Laminaria tent + prostaglandins versus prostaglandins alone</u> Maternal and neonatal outcomes were similar between the two groups (4 RCTs)</p> <p><u>Balloon catheter + prostaglandins versus prostaglandins alone</u> Vaginal birth within 24 hours (1 RCT): RR 0.32 (95% CI 0.12 to 0.8)</p> <p><u>Any mechanical method versus misoprostol</u> Vaginal birth not achieved in 24 hours (4 RCTs): 34% versus 30%, RR 1.15 (95% CI 0.80 to 1.66) Hyperstimulation with FHR changes (4 RCTs): 4% versus 9%, RR 0.41 (95% CI 0.20 to 0.87) Caesarean birth: 27% versus 22%, RR 1.22 (95% CI 0.93 to 1.61) Serious maternal and neonatal morbidity was infrequent.</p> <p><u>Any mechanical method versus oxytocin</u> Achieving vaginal birth within 24 hours: no data Hyperstimulation with FHR changes: no data Serious maternal and neonatal morbidity: no data Caesarean birth (4 RCTs): 17% versus 32% RR 0.55 (95% CI 0.33 to 0.91) Hyperstimulation without FHR changes: RR 0.50 (95% CI 0.05 to 5.22)</p> <p><u>Laminaria tent versus oxytocin</u> The risk of caesarean birth was similar (2 RCTs).</p> <p><u>Laminaria tent + oxytocin versus oxytocin alone</u> Maternal and neonatal outcomes were similar between the two groups (1 RCT).</p> <p><u>Balloon catheter versus oxytocin</u> Caesarean birth (2 RCTs): RR 0.43 (95%CI 0.22 to 0.83)</p>	

Bibliographic details	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
					<p><u>Extra-amniotic infusion versus any prostaglandins</u> Not achieved vaginal birth within 24 hours (5 RCTs): 57% versus 22%, RR (95% CI 1.14 to 1.90) Hyperstimulation with FHR changes: RR 0.66 (95% CI 0.30 to 1.46) Serious maternal and neonatal morbidity was infrequent.</p> <p><u>Laminaria versus extra-amniotic saline infusion</u> Maternal and neonatal outcomes were similar between the two groups (2 RCTs)</p>	
Afolabi (2005) ¹⁷²	Study Type: Randomised controlled trial Evidence level: 1+	Total number of women = 57 Intravaginal misoprostol 100 µg n = 29 Foley catheter insertion n = 28	Women requiring cervical priming Bishop score < 5 Nullipara: 26 Multipara: 31	Single dose of intravaginal misoprostol 100 µg versus Foley catheter insertion.	Induction to delivery interval (hours): 11.84 (5.43) versus 20.03 (4.68) (P < 0.05) Change in Bishop score: 6.6 (1.7) versus 4.4 (1.93) (P < 0.05) Vaginal birth within 24 hours: 100% versus 82% (P < 0.05) Intrapartum complications: NS Caesarean section: 36% versus 32% (NS)	Source of Funding: Not stated Computer randomisation, allocation codes in opaque, sealed envelopes, no power calculation.
Chung (2003) ¹⁷³ Country: US	Study Type: Randomised controlled trial Evidence level: 1+	Total number of women = 146 Intracervical misoprostol n = 49 Intracervical Foley catheter insertion n = 54 Combination misoprostol-Foley catheter n = 43	Women requiring induction of labour, mixed parity and Bishop score ≤ 6	Intracervical misoprostol versus Intracervical Foley catheter insertion versus combination misoprostol-Foley catheter.	All vaginal births: 63% versus 57% versus 58% (NS) CS: 37% versus 43% versus 42% (NS) Induction-to-delivery interval (hr): 18 versus 20 versus 17 (NS) Epidural use: 80% versus 70% versus 84% (NS) Tachysystole: 63% versus 30% versus 47% (P = 0.03) Hyperstimulation: 33% versus 11% versus 16% (P = 0.02) Meconium: 14% versus 17% versus 16% (NS) Chorioamnionitis: 6% versus 9% versus 21% (P = 0.07)	Source of Funding: Memorial Medical Center Foundation, US Randomisation with use of Epistat with a block size of 10, allocation in consecutively numbered, opaque and sealed envelopes. Women and treating physician not blind. Power calculation.

6 Setting and timing for induction of labour

Bibliographic details	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
Oei (2000) ¹⁷⁸ Country: The Netherlands	Study Type: Randomised controlled trial Evidence Level: 1+	Total women = 126 Endocervical PGE ₂ gel 0.5 mg in morning between 0.800 – 0900 hours <i>n</i> = 58 Endocervical PGE ₂ gel 0.5 mg in evening between 22.00 – 23.00 hours <i>n</i> = 68	Women at term (Bishop score < 6) scheduled for induction of labour.	Endocervical PGE ₂ gel 0.5 mg in morning between 0.800 – 0900 vs endocervical PGE ₂ gel 0.5 mg in evening between 22.00 – 23.00 hours.	Delivery between 18.00 and 08.00 hours: 9 versus 9 (NS) Vacuum/forceps delivery in nulliparous women: 3 versus 19 (RR 4.2, 95% CI 1.4 to 13) CS: 7 versus 5 (NS) Maternal satisfaction: 77% versus 62% Report of bad sleep: 34% versus 73%, RR 1.7 (95% CI 1.1 to 2.5) Would choose the same time of induction in next pregnancy: 8% versus 23%, RR 2.4 (95% CI 0.86 to 6.6)	Source of Funding: not reported Randomisation using random number table, concealment by means of sequentially numbered sealed envelopes, power calculation.
Dodd (2006) ¹⁷⁷ Country: Australia	Study Type: Randomised controlled trial Evidence level: 1+	Total number of women = 620 Morning admission (0800 hours) for induction of labour <i>n</i> = 280 Evening admission (2000 hours) for induction of labour <i>n</i> = 340	Women at = 36 +6 weeks of gestation	Morning admission (0800 hours) for induction versus evening admission (2000 hours) for induction.	Achieving vaginal birth within 24 hours: 43% versus 44% (NS) Incidence of uterine hyperstimulation with FHR changes: 2% versus 0% (NS) Caesarean birth: 22% versus 26% (NS) Women's satisfaction: disliked lack of sleep: 0.4% vs 4.4% (RR 0.08, 95% CI 0.01 to 0.61) Maternal complications: NS Fetal complications: NS	Source of Funding: Royal Australian and NZ College Obs & Gynae Computer generated randomisation, not blinded, power calculation.
Biem (2003) ¹⁷⁴ Country: Canada	Study Type: Randomised controlled trial Evidence level: 1+	Total number of women = 300 Out patient induction of labour with controlled-release	Women at term (~ 80% postdates) with a Bishop score of = 6.	Out patient induction of labour with controlled-release PGE ₂ versus inpatient induction of labour with controlled-release PGE ₂ .	Delivery by 24 hours: 77% versus 71% (NS) Median time to delivery (hrs): 21.4 versus 20.7 (NS) CS: 23% versus 25% (NS) Apgar score at 5 minutes (median): 8.81 versus 8.71 (NS)	Source of Funding: Not reported Computer generated randomisation, no power calculation.

Bibliographic details	Study type and evidence level	Number of patients	Patient characteristics	Intervention and comparison	Follow-up and outcome measures effect size	Reviewer comments
		PGE ₂ <i>n</i> = 150				
		Inpatient abour induction with controlled-release PGE ₂ <i>n</i> = 150				
Somerset (1995) ¹⁷⁹ Country: UK	Study Type: Cohort Evidence level: 2+	Total number of women = 80 Induction of labour with vaginal PGE ₂ gel 2 mg inserted at 1400 hours <i>n</i> = 40 Induction of labour with vaginal PGE ₂ gel 2 mg inserted at 2200 hours <i>n</i> = 40	Women at 37–42 weeks of gestation scheduled for induction of labour	Induction of labour with vaginal PGE ₂ gel 2 mg inserted at 1400 hours versus induction of labour with vaginal PGE ₂ gel 2 mg inserted at 2200 hours	Forceps birth: 27% versus 33% (NS) CS: 10% versus 25% (NS) Days in hospital: 4.4 versus 5.3 (<i>P</i> < 0.01) Total costs of admission (£): 1461 versus 1811 (<i>P</i> = 0.01)	Source of Funding: not reported
Sciscione (2001) ¹⁷⁵ Country: US	Study Type: Randomised controlled trial Evidence level: 1+	Total number of women = 111 Outpatient cervical priming with transcervical Foley catheter <i>n</i> = 61 Inpatient cervical priming with transcervical Foley catheter <i>n</i> = 50	Women at term and a Bishop score < 5.	Outpatient cervical priming with transcervical Foley catheter vs inpatient cervical priming with transcervical Foley catheter.	Change in Bishop score: 3.0 versus 3.0 (NS) CS: 29% versus 43% (NS) Apgar score at 5 minutes: 0 versus 8.0 (NS) Maternal discomfort (1–10 visual analogue scale, 1 being no discomfort and 10 worst pain): 4.8 (2.4) versus 3.9 (2.3) (NS)	Source of Funding: not reported Computer generated randomisation, no power calculation.

7 Monitoring and pain relief for induction of labour

7.2 Pain relief during induction of labour

Bibliographic Information	Study type and evidence level	Aim of study	Number of patients and patient characteristics	Population characteristics	Outcome measures	Reviewer comments
Chen (2000) ¹⁸² Country: Taiwan	Study Type: Randomised controlled trial Evidence level: 1+		Total number of women = 120 Epidural (fentanyl) to relieve early first stage of labour pain during the early period of the first stage of induced labour (IV oxytocin) <i>n</i> = 60 (Group A) No epidural (fentanyl) to relieve early first stage of labour pain during the early period of the first stage of induced labour (IV oxytocin) <i>n</i> = 60 (Group B) Convenience control sample (no analgesia during entire labour course) <i>n</i> = 198 (Group C)	Women undergoing induction of labour.	CS: Groups A, B and C: 17% versus 15% versus 29% Group A vs B [NS]; Group A vs C, <i>P</i> = 0.09; Group B vs C, <i>P</i> = 0.05 Pain scores (VAS visual analogue scale): Lower in group A than in group B and C (<i>P</i> < 0.001) Duration of labour: early first stage: Groups A vs B vs C (NS) Apgar score at 5 minutes: Groups A vs B vs C (NS) Quality of analgesia rated as 'excellent': Group A 80% vs Group B 0% (<i>P</i> < 0.001)	Funding: National Science Council, Republic of China Methods of randomisation not reported, no power calculation.
Balladur (1989) ¹⁸³ Country: France	Study Type: Randomised controlled trial Evidence level: 1+		Total number of women = 88 Epidural (fentanyl) started at beginning of induction <i>n</i> = 41 Epidural (fentanyl) once labour became 'active'	Women at term (37 - 42 weeks of gestation) undergoing induction (oxytocin).	Duration of labour (mins): Primiparous: 445 Multiparous: 213 Primiparous: 360 (<i>P</i> < 0.05) Multiparous: 282 (<i>P</i> < 0.05) Forceps birth: 6 versus 9 CS: 2 versus 4	Funding: not stated Methods of randomisation not reported No power calculation

Bibliographic Information	Study type and evidence level	Aim of study	Number of patients and patient characteristics	Population characteristics	Outcome measures	Reviewer comments
			<i>n</i> = 47		Assisted births: 0 versus 4	
Capogna (2001) ¹⁸¹	Study Type: Cohort	To compare analgesia requirement of women in spontaneous labour and in induced labour	Total number of women = 61 Spontaneous labour <i>n</i> = 30 Induction of labour (with PGE ₂) <i>n</i> = 31	Women (= 37 weeks of gestation with cervical dilation 2–4 cm) requesting epidural pain relief in labour.	Minimum analgesic dose of sufentanil: 22.2 µg (95% CI 19.6 to 22.8) 27.3 µg (95% CI 23.8 to 30.9) (<i>P</i> = 0.0014) by a factor of 1.3 (95% CI 1.1 to 1.5) Duration of analgesia: 88 minutes versus 95 minutes (NS) Sedation (measured by VAS): 55 (34–70) versus 70 (50–80) (<i>P</i> = 0.024) Nausea (measured by VAS): 0 versus 1 (NS) Maternal hypotension (< 90 mmHg): 0 versus 3 (NS)	Funding: not stated Prospective, double-blind study, sequential allocation: to reduce bias from confounders.

8 Complications of induction of labour

8.1 Uterine hyperstimulation

Bibliographic details	Study type and evidence level	Aim of study	Number of patients and patient characteristics	Population characteristics	Outcome measures	Reviewer comments
Egarter (1990) ¹⁸⁵	Study Type: Other Evidence level: 3	To review the frequency of uterine hyperstimulation associated with PGE ₂ use and describe the therapeutic effects of B2-adrenergic tocolytic therapy.	Total number of women = 3099	Maternity cases requiring low dose PGE ₂ (vaginal tablet, gel and intracervical gel) therapy for induction of labour.	Uterine hyperstimulation in 181 cases (5.8%) 31.5% had FHR abnormalities Administration of tocolytic treatment with B-adrenergic drugs (hexoprenaline at 0.3 µg/minute or a single dose of terbutaline 250 µg intravenously or subcutaneously): Uterine contractions normalised and reversing any FHR abnormality in 178 cases (98.3%) Caesarean : 3 postpartum complications: 0	Source of Funding: not reported Uterine hyperstimulation defined as contraction frequency was more than 5 in 10 minutes or if contractions exceeded 2 minutes in duration. Non-comparative study: likelihood of confounders.

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