

Understanding NICE guidance

Information for people who use NHS services

Amnioinfusion for oligohydramnios during pregnancy

NICE 'interventional procedures guidance' advises the NHS on when and how new surgical procedures or procedures that use electromagnetic radiation (such as X-rays, lasers and gamma rays) can be used.

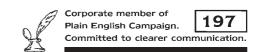
This leaflet is about when and how amnioinfusion can be used to treat pregnant women with oligohydramnios (insufficient amniotic fluid) in the NHS in England, Wales, Scotland and Northern Ireland. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence). This leaflet does not cover amnioinfusion during labour.

NICE has produced this guidance because the procedure is quite new. This means that there is not a lot of information yet about how well it works, how safe it is and which patients will benefit most from it.

This leaflet is written to help parents who have been offered this procedure to decide whether to agree (consent) to it or not. It does not describe oligohydramnios or amnioinfusion in detail – a member of your healthcare team should also give you full information and advice about these. The leaflet includes some questions you may want to ask your doctor to help you reach a decision. Some sources of further information and support are on the back page.

Interventional procedures guidance makes recommendations on the safety of a procedure and how well it works. The guidance does not cover whether the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering how well the procedure works and whether it represents value for money for the NHS.

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What has NICE said?

There are still uncertainties over the safety of this procedure and how well it works. If a doctor wants to use amnioinfusion he or she should make sure that extra steps are taken to explain the uncertainty and the likely benefits and potential risks of the procedure. This should happen before the parents agree (or don't agree) to the procedure. The parents should be given this leaflet and other written information as part of the discussion. There should also be special arrangements for monitoring what happens after the procedure.

This procedure should only be carried out in a specialist centre, by a team that may include a consultant in fetal medicine, a neonatologist and a specialist midwife.

Further information on the safety of amnioinfusion and how well it works will be helpful. NICE has encouraged doctors to ask patients to take part in clinical trials looking at amnioinfusion for oligohydramnios. NICE may look at this procedure again if more information becomes available.

This procedure may not be the only possible treatment for oligohydramnios. Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.

Amnioinfusion

The procedure is not described in detail here – please talk to your obstetrician for a full description.

Oligohydramnios is the medical term for having too little amniotic fluid around the baby in the womb. It has many different possible causes. Severe oligohydramnios early in a pregnancy may affect the way the unborn baby grows.

Oligohydramnios is not generally treated. Usually, the doctor checks the growing baby regularly and allows nature to take its course. In amnioinfusion, a solution that is similar to amniotic fluid is injected through the mother's abdomen (belly) and into the space around the baby. The doctor uses ultrasound to watch what he or she is doing. The procedure can be done several times (which is called serial amnioinfusion).

What does this mean for me?

If your doctor has offered you amnioinfusion for oligohydramnios, he or she should tell you that NICE has decided that the benefits and risks are uncertain. This does not mean that the procedure should not be done, but that your doctor should fully explain what is involved in having the procedure and discuss the possible benefits and risks with you. You should only be asked if you want to agree to this procedure after this discussion has taken place. You should be given written information, including this leaflet, and have the opportunity to discuss it with your doctor before making your decision.

NICE has also decided that more information is needed about amnioinfusion. So it has recommended that some details should be collected about every patient who has this procedure in England and Wales. These details will be held confidentially and will not include patients' names. The information will be used only to see how safe the procedure is and how well it works. If you decide to have amnioinfusion, you will be asked to agree to your details being entered into an electronic database for this purpose. If you do not agree to the details being entered into an electronic database, you can still have the procedure.

You may want to ask the questions below

- What does the procedure involve?
- What are the benefits my unborn baby might get?
- How good are the baby's chances of getting those benefits?
- Are there alternative procedures?
- What are the risks of the procedure?
- Are the risks minor or serious? How likely are they to happen?
- What care will I and the baby need after the operation?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

Summary of possible benefits and risks

Some of the benefits and risks seen in the studies considered by NICE are briefly described below. NICE looked at eight studies on this procedure.

How well does the procedure work?

One study showed that amnioinfusion reduced the risk of babies being born with poorly developed lungs, but another study showed that amnioinfusion made little difference You might decide to have this procedure, to have a different procedure, or not to have a procedure at all. Three studies showed that amnioinfusion increased the chances of babies living after birth. In women who were treated, two out of 11 (18%), 6 out of 26 (23%) and 3 out of 11 (27%) babies died. In women who were not treated 5 out of 7 (71%), 5 out of 13 (38%) and 23 out of 29 (79%) babies died. One other study showed no difference in the survival of babies born to women who were treated and women who were not treated.

Risks and possible problems

In a study of 45 women treated with amnioinfusion, 1 went into labour soon after the procedure. Miscarriage occurred in 11–21% of women in another study and was more likely if the membranes had ruptured.

Amnioinfusion seemed to reduce the number of babies who died in the womb. In four studies, up to 14% of babies whose mothers were treated died, compared with up to 38% of babies whose mothers were not treated.

Other problems were placental abruption (where the placenta comes away from the womb), which occurred in up to 25% of pregnancies, and infection of the membranes and fluid (chorioamnionitis) in up to 32%. One baby was born with a cut to the leg, which required stitches.

More information about oligohydramnios in pregnancy

NHS Direct online (www.nhsdirect.nhs.uk) may also be a good starting point for finding out more. Your local Patient Advice and Liaison Service (PALS) may also be able to give you further advice and support.

About NICE

NICE produces guidance (advice) for the NHS about preventing, diagnosing and treating different medical conditions. The guidance is written by independent experts including healthcare professionals and people representing patients and carers. They consider how well an interventional procedure works and how safe it is, and ask the opinions of expert advisers. Staff working in the NHS are expected to follow this guidance.

To find out more about NICE, its work and how it reaches decisions, see www.nice.org.uk/aboutguidance

This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/IPG192

You can order printed copies of this leaflet from the NHS Response Line (phone 0870 1555 455 and quote reference N1135).

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