

Image-guided ultrasound treatment for uterine fibroids

NICE 'HealthTech guidance' advises the NHS on when and how new procedures can be used in clinical practice.

This leaflet is about when and how image-guided ultrasound can be used in the NHS to treat women with uterine fibroids. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

This HealthTech guidance makes recommendations on the safety of a procedure and how well it works. An interventional procedure is a test, treatment or surgery that involves a cut or puncture of the skin, or an endoscope to look inside the body, or energy sources such as X-rays, heat or ultrasound. The guidance does not cover whether or not 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.

This leaflet is written to help people who have been offered this procedure to decide whether to agree (consent) to it or not. It does not describe uterine fibroids or the procedure 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 page 6.

What has NICE said?

There is evidence to say that this procedure works in the short term, although further treatment may be needed and the possibility of future successful pregnancies is not certain. There are well-known complications, but the evidence on safety is adequate. This procedure can be therefore offered routinely as a treatment option for women with uterine fibroids provided that doctors are sure that:

- the woman understands what is involved and agrees to the treatment, and
- the results of the procedure are monitored.

The woman should be told that her symptoms may not be relieved, that they may return, and that further procedures may be needed. She should also be told that there is a risk of skin burns. Women who may wish to become pregnant later should be told that the effects of the procedure on fertility and pregnancy are uncertain.

A healthcare team that is experienced in managing uterine fibroids should decide which women should be offered this procedure. The team should include a gynaecologist and an imaging specialist. This procedure should only be carried out by doctors with specific training in the procedure.

NICE has encouraged further research into this procedure, including what happens in the long term and the need for further treatment. Information on pregnancies in women who choose this procedure because they want to maintain or improve their fertility is particularly important.

Other comments from NICE

NICE noted that many women wish to avoid more invasive treatment for uterine fibroids, even if there is a higher chance of needing further treatment. The Committee also noted that new and improved techniques for this procedure are being developed.

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

Image-guided ultrasound treatment for uterine fibroids

The medical name for this procedure is ‘magnetic resonance image-guided transcutaneous focused ultrasound for uterine fibroids’.

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

Uterine fibroids are common non-cancerous (benign) growths that occur in the womb (uterus). They can cause bleeding, urinary incontinence, and a feeling of pressure or pain in the abdomen. Fibroids can also sometimes make it difficult for a woman to conceive or carry a pregnancy to term.

Symptomatic fibroids are often treated with a hysterectomy, in which the whole womb is removed, or with a myomectomy, in which just the fibroids are removed. Other treatments involve procedures to block the blood supply to the fibroids or to remove the lining of the womb.

Image-guided ultrasound treatment is a less invasive technique designed to reduce the symptoms of fibroids. It is usually carried out with the woman conscious but sedated. A fine tube (catheter) is inserted to keep her bladder empty during the procedure. During treatment, the woman lies on her front in a special scanner that combines magnetic resonance imaging (MRI) with ultrasound. She is able to let the operator know if she experiences any discomfort (for example, burning sensations or pain). The ultrasound device is placed in contact with the woman’s skin on the lower abdomen. Low-power ultrasound is first used to target the fibroid, then high-power ultrasound is used to heat and destroy part or all of the fibroid. Treatment may last for up to 3 hours.

What does this mean for me?

NICE has said that this procedure is safe enough and works well enough for use in the NHS. If your doctor thinks image-guided ultrasound is a suitable treatment option for you, they should still make sure you understand the benefits and risks before asking you to agree to it.

NICE has also said that more information is needed about this procedure. Your doctor may ask you if details of your procedure can be used to help collect more information about this procedure. Your doctor will give you more information about this.

You may want to ask the questions below

- What does the procedure involve?
- What are the benefits I might get?
- How good are my chances of getting those benefits? Could having the procedure make me feel worse?
- 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 need after the procedure?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

You might decide to have this procedure, to have a different procedure, or not to have a procedure at all.

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 9 studies on this procedure.

How well does the procedure work?

A study of 192 women treated by the procedure or by hysterectomy reported that both procedures improved the women's quality of life, with greater improvements at 6 months in women treated by hysterectomy.

A study of 40 patients who had the procedure reported significant improvements in both symptom severity and quality of life when their progress was checked after 3 years.

In two studies of a total of 210 women who had the procedure, 15 had a hysterectomy within 1 year of treatment.

A study of 51 women who conceived after having the procedure reported that of the 54 pregnancies, 22 babies were born, 14 of the pregnancies ended in miscarriage and 7 were terminated at the request of the woman.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that the main success factors are quality of life, improved symptoms, avoidance of further procedures and maintained or improved fertility.

Risks and possible problems

In the study of 192 women, temporary injury of the sciatic nerve causing weakness in the leg was reported in 1 of the 109 women who had the procedure. In the study of 80 women who had the procedure, 1 temporarily experienced mild pain associated with the sciatic nerve.

In a study of 287 women, skin burns were reported in 10 of 144 women who had the procedure between 2003 and 2005, and in 2 of 143

women treated between 2005 and 2006. One woman who had the procedure had a severe burn in the lower abdomen, which needed surgery.

One woman who had the procedure needed surgery to remove the treated fibroid tissue. There was also a report of a woman whose bowel was damaged and who needed surgery.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that in theory another possible problem was bladder damage.

More information about uterine fibroids

NHS Choices (www.nhs.uk) may be a good place to find out more. Your local patient advice and liaison service (usually known as PALS) may also be able to give you further information and support. For details of all NICE guidance on uterine fibroids, visit our website at www.nice.org.uk

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. HealthTech guidance applies to the whole of the NHS in England, Wales, Scotland and Northern Ireland. 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 is about 'magnetic resonance image-guided transcutaneous focused ultrasound for uterine fibroids'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/guidance/HTG277

The NICE website has a screen reader service called Browsealoud, which allows you to listen to our guidance. Click on the Browsealoud logo on the NICE website to use this service.

We encourage voluntary organisations, NHS organisations and clinicians to use text from this booklet in their own information about this procedure.

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