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Information for the public

National Institute for Health and Clinical Excellence

Treating chronic low back pain by peripheral nerve-field stimulation

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

This document is about when and how peripheral nerve-field stimulation can be used in the NHS to treat people with chronic low back pain. 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.

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 document 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 back pain or the procedure in detail – a member of your healthcare team should give you full information and advice about these. The document 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 7.

What has NICE said?

There is not much good evidence about how well this procedure works, how safe it is, or how long the effects last. If a doctor wants to use peripheral nerve-field stimulation for chronic low back pain, they should make sure that extra steps are taken to explain the uncertainty about how well it works, as well as the uncertainty surrounding potential risks of the procedure. This should happen before the patient agrees (or doesn't agree) to the procedure. The patient should be given this document and other written information as part of the discussion. There should also be special arrangements for monitoring what happens to the patient after the procedure.

A team of healthcare professionals who are experienced in managing chronic low back pain should decide which patients should have this procedure. The team should include specialists in pain management and neurosurgery.

NICE is asking doctors to send information about everyone who has the procedure and what happens to them afterwards to a database at the UK Neuromodulation Register when it is available so that the safety of the procedure and/or how well it works can be checked over time.

NICE has encouraged publication of further research into peripheral nerve-field stimulation for chronic low back pain.

Treating chronic low back pain by peripheral nerve-field stimulation

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

'Chronic' means that the pain lasts for a long time. Peripheral nerves are those not in the brain or spinal cord.

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

Chronic low back pain is usually caused by 'wear and tear' changes in the discs and joints of the lumbar spine. It is usually treated with painkillers, lifestyle advice, posture training, exercises, manual therapies (such as physiotherapy) or acupuncture. If these don't work, surgery may be considered.

This procedure involves electrically stimulating the lower back area. The aim is to mask the pain by producing a tingling sensation. It is less invasive than other types of surgery and is a reversible method of pain control that may be useful for people with severe and difficult-to-treat pain.

The procedure is usually done in 2 stages. The patient is given a local anaesthetic. Leads containing electrodes are implanted under the skin in the lower back. The leads are then connected to a device called a hand-held neurostimulator, which produces electrical pulses. The surgeon tests the stimulation effect to make sure the electrodes are in the right place. The patient uses the neurostimulator to stimulate the nerves when needed and tests the device over several days. If this trial period is successful, the patient has another operation using local anaesthetic in which a neurostimulator is implanted under the skin and connected by leads under the skin to the electrodes already inserted during the first operation. The patient operates the device using a remote control. The system can be removed.

What does this mean for me?

If your doctor has offered you peripheral nerve-field stimulation for chronic low back pain, 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 document, and have the opportunity to discuss it with your doctor before making your decision.

NICE has also decided 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 5 studies on this procedure.

How well does the procedure work?

Four studies tested whether the procedure reduced the severity of low back pain. In all studies, all 104 patients treated for low back pain and 37 patients treated for back pain that hadn't been helped by surgery had improvements in pain scores after the procedure over a period of up to a year. In 1 study, 16 out of 18 patients were able to reduce or stop taking painkillers after a year, and in another study 7 out of 13 patients were able to reduce painkiller use.

In one of the studies (of 13 patients), 9 patients were satisfied or very satisfied with the procedure.

As well as looking at these studies, NICE also asked expert advisers for their views. They said that the main things that needed to be measured to see whether the procedure had been a success were the severity of pain, how disabling the pain was, how it affected patients' lives, medication use, and how quickly patients were able to return to normal activities.

Risks and possible problems

In a study of 18 patients, 1 patient got an infection where the device had been implanted. It had to be removed but was later put back in. The device had to be reprogrammed in 12 patients within the first 6 weeks and 3 patients needed additional help to learn how to recharge the device.

In a study of 10 patients, the electrode moved and had to be repositioned in 1 patient after 3 weeks.

As well as looking at these studies, NICE also asked expert advisers for their views. They said that possible problems include bleeding after the procedure or the leads breaking. They also said that in theory, other problems could include skin erosion (breaking down), damage to internal organs (although this is considered very unlikely, even in very thin patients), and haematoma (collection of blood under the skin).

More information about low back pain

NHS Choices (www.nhs.uk) may be a good place to find out more.

For details of all NICE guidance on low back pain, 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 document is about 'Peripheral nerve-field stimulation for chronic low back pain'. This document and the full guidance aimed at healthcare professionals are available at guidance.nice.org.uk/HTG309

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

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

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