NICE National Institute for Health and Care Excellence

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Information for the public

Treating intractable chronic migraine by stimulating nerves at the back of the head

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 stimulating nerves at the back of the head can be used in the NHS to treat people with intractable chronic migraine. It explains guidance (advice) from NICE (the National Institute for Health and Care 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 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 migraine 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 8.

What has NICE said?

There is some evidence that this procedure works in the short term but very little in the long term. There is a risk of complications, which may need further surgery. If a doctor wants to use this procedure for intractable chronic migraine, 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 healthcare team experienced in managing chronic migraine should decide which patients should have this procedure. The team should include specialists in headache, 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 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 the stimulation of nerves at the back of the head for intractable chronic migraine.

Treating intractable chronic migraine by stimulating nerves at the back of the head

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

The medical name for this procedure is 'occipital nerve stimulation for intractable chronic migraine'.

'Chronic' means that the pain lasts for a long time and 'intractable' means that it doesn't respond to treatment.

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

Migraine is a severe headache often accompanied by other symptoms such as sensitivity to light and sound. It is usually treated by painkillers or other drugs but if they don't work, more invasive options include nerve blocks (injections around the nerves to control the pain), botulinum toxin (Botox) or acupuncture.

This procedure involves electrically stimulating the occipital nerves, which are at the back of the head, at the base of the skull. The aim is to mask the pain by producing a tingling sensation.

The procedure is usually done in 2 stages, although sometimes it is only one. The patient is given a local anaesthetic. Leads containing electrodes are implanted under the skin at the back of the neck over the nerve. The leads are then connected to a handheld device called a neurostimulator, which produces electrical pulses. The surgeon turns on the neurostimulator and tests it is working by asking the patient what sensations they are feeling. The leads are then stitched into place under the skin. The patient uses the neurostimulator to stimulate the nerves when needed and tests it over several days. If the initial trial period is successful, a neurostimulator is implanted under the skin (under general anaesthetic), in the chest or abdomen (belly), with a lead

running under the skin to the electrodes. The patient uses a remote control to stimulate the nerves when needed.

What does this mean for me?

If your doctor has offered you this procedure, 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 3 studies on this procedure.

How well does the procedure work?

Three studies tested whether nerve stimulation reduced the number and severity of patients' headaches.

In the first study, 157 patients were scored out of 200 based on the number of days they had headaches and what effect it had on them (a high score meant worse headaches). Scores 3 months after having the procedure had dropped by 65 points for the 105 patients who had nerve stimulation but by just 20 for the 52 patients who had sham stimulation (in which the device was implanted but not turned on). There was no real difference between the groups in the proportion of patients whose pain reduced by 50% or more.

The second study (67 patients) measured 'response', defined as either the number of headache days dropping by 50% more, or the intensity of pain reducing by at least 3 points (out of 10). Eleven of the 28 patients having nerve stimulation, 1 of the 16 patients having sham stimulation, and none of the 17 patients treated with painkillers or other drugs had responded when they were checked after 3 months.

In the third study, all 25 patients had nerve stimulation. At the start of the study, patients had an average of 76 headaches every 90 days and rated their headaches as 9 out of 10 for severity. After an average of 18 months of treatment, this had dropped to 38 headaches every 90 days on average and 6 out of 10 for severity.

As well as looking at these studies, NICE also asked expert advisers for their views. They said that the success factors were a reduction in: the number of migraine or headache days, headache severity, how often and how long they last for, how disabling they are and medication use; and an improvement in patients' quality of life.

Risks and possible problems

Out of a total of 208 patients in 2 studies, 14 had infections where the device had been implanted. In the study of 157 patients, after 3 months it was found that the leads had broken through the skin in 6 patients.

Within 18 months, the leads had moved out of place in 41 patients out of 227 patients from 3 studies – this happened within 3 months in 32 of the patients.

There were problems with programming the device in 6 patients and with the leads in 2 patients out of 51 in 1 study.

In the study of 157 patients, 23 had constant pain or numbness where the device or leads had been implanted and 1 patient having nerve stimulation lost motor or musculoskeletal control (so they couldn't control how their body moved).

In the same study, 6 patients having nerve simulation and 1 having sham stimulation said they had experienced stimulation despite not activating the neurostimulator.

As well as looking at these studies, NICE also asked expert advisers for their views. They said that, in theory, things that could go wrong included bleeding, nerve damage and the lead breaking.

More information about migraine

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

For details of all NICE guidance on migraine, visit our website at www.nice.org.uk

About NICE

NICE provides national guidance and advice to improve health and social care. Interventional procedures 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 'occipital nerve stimulation for intractable chronic migraine'. This document and the full guidance aimed at healthcare professionals are available at guidance.nice.org.uk/HTG310

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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