

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedure consultation document

MRI-guided focused ultrasound thalamotomy for treatment-resistant essential tremor

Essential tremor has no known cause but may get worse with time and be resistant to treatment. This procedure uses a special head frame that allows the delivery of focused ultrasound to destroy a specific area of the brain (thalamus) under MRI guidance. The aim is to reduce the patient's tremor.

The National Institute for Health and Care Excellence (NICE) is looking at MRI-guided focused ultrasound thalamotomy for treatment-resistant essential tremor. NICE's interventional procedures advisory committee has considered the evidence and the views of specialist advisers, who are consultants with knowledge of the procedure.

The committee has made draft recommendations and we now want to hear your views. The committee particularly welcomes:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

This is not our final guidance on this procedure. The recommendations may change after this consultation.

After consultation ends:

- The committee will meet again to consider the original evidence and its draft recommendations in the light of the consultation comments.
- The committee will prepare a second draft, which will be the basis for NICE's guidance on using the procedure in the NHS.

For further details, see the [Interventional Procedures Programme process guide](#).

Through our guidance, we are committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in developing our interventional procedures guidance. In particular, we encourage people and organisations from groups who might not normally comment on our guidance to do so.

To help us promote equality through our guidance, please consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that we reserve the right to summarise and edit comments received during consultations or not to publish them at all if in the reasonable opinion of NICE, there are a lot of comments, or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 23 November 2017

Target date for publication of guidance: February 2018

1 Draft recommendations

- 1.1 Current evidence on the safety and efficacy of MRI-guided focused ultrasound thalamotomy for treatment-resistant essential tremor is inadequate in quantity and quality. Therefore, this procedure should only be used in the context of research.
- 1.2 Further research, which could include randomised controlled trials, should address patient selection and report on long-term follow-up.

2 The condition, current treatments and procedure

The condition

- 2.1 Essential tremor is the most common cause of disabling tremor and is distinct from Parkinson's disease. It typically affects the arms and hands, although it may also involve the head, jaw, tongue and legs. The cause is not known but many patients have a family history of the condition. At first, the tremor may not be present all the time. However, it gradually worsens. Purposeful movement, stress, tiredness, hunger, heightened emotions or extremes in temperature make it worse.

Current treatments

- 2.2 Treatment for essential tremor includes medications such as beta blockers (for example, propranolol), anti-epileptics (for example, primidone) or sedatives (for example, clonazepam). Rarely, injections of botulinum toxin may be used.
- 2.3 Surgery may be considered in people whose condition has not responded adequately to best medical therapy. Surgical treatments include deep brain stimulation and radiofrequency thalamotomy.

The procedure

- 2.4 This procedure is carried out with the patient lying supine inside an MR scanner. The patient's head is shaved and a stereotactic head frame is attached. Patients are kept awake so they can report any improvement or adverse events to the operator during the procedure. However, they may be offered light sedation.

Continuous MR imaging and thermal mapping are used to identify the target area of the brain and monitor treatment. Low power (sub-lethal) ultrasound is delivered to confirm the chosen location. Then, high-power focused ultrasound pulses are administered to irreversibly ablate target tissue. Chilled water is circulated around the head during the treatment to prevent thermal damage to the scalp caused by the increase in bone temperature. The procedure takes about 3 hours and symptom relief should be immediate.

- 2.5 The potential benefits of MRI-guided focused ultrasound thalamotomy are that it: is less invasive than the other existing procedures; results in a faster recovery time; and allows for testing of the effects of sub-lethal doses before ablation. However, unlike deep brain stimulation, it can only be done on 1 side

3 Committee considerations

The evidence

- 3.1 To inform the committee, NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 5 sources, which was discussed by the committee. The evidence included 1 randomised controlled trial and 4 case series, and is presented in table 2 of the [interventional procedure overview](#). Other relevant literature is in appendix A of the overview.
- 3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: sustained reduction in tremor, improved quality of life and functional improvement.

- 3.3 The specialist advisers and the committee considered the key safety outcomes to be: unintentional neurological consequences and intracerebral bleeding.
- 3.4 No patient commentary was sought because this procedure is currently only done in research in the UK.

Committee comments

- 3.5 The device used for MRI-guided focused ultrasound thalamotomy is CE marked for use in unilateral procedures, so the procedure can only treat tremor on 1 side of the body.
- 3.6 There is a comprehensive training programme offered by the company manufacturing the device used in this procedure.
- 3.7 The committee noted that essential tremor can have major consequences on the quality of life for many people.

Tom Clutton-Brock
Chairman, interventional procedures advisory committee
October 2017

ISBN: