

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

Interventional procedures guidance

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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Recommendations

- 1.1 The evidence on the safety of unilateral MRI-guided focused ultrasound thalamotomy for treatment-resistant essential tremor raises no major safety concerns. However, current evidence on its efficacy is limited in quantity. Therefore, this procedure should not be used unless there are special arrangements for clinical governance, consent, and audit or research. Find out what special arrangements mean on the NICE interventional procedures guidance page.
- 1.2 Clinicians wishing to do unilateral MRI-guided focused ultrasound thalamotomy for treatment-resistant essential tremor should:
 - Inform the clinical governance leads in their NHS trusts.
 - Ensure that patients and their carers understand that this procedure is only done to treat tremor on 1 side of the body, and that the effect of this on the functional ability and quality of life of patients with bilateral disease is uncertain. Patients should be informed about alternative treatments, including those that can be done bilaterally. Provide patients with clear written information to support shared decision-making. In addition, the use of NICE's information for the public on unilateral MRI-guided focused ultrasound thalamotomy for treatment-resistant essential tremor is recommended.
 - Audit and review clinical outcomes of all patients having unilateral MRI-guided focused ultrasound thalamotomy for treatment-resistant essential tremor. NICE has identified relevant audit criteria and has developed NICE's interventional

procedure outcomes audit tool (which is for use at local discretion).

- 1.3 Patient selection should be done by a multidisciplinary team experienced in managing essential tremor, including clinicians with specific training in the procedure.
- 1.4 Further research, which could include randomised controlled trials, should address patient selection, report on functional improvement and quality of life, and provide long-term follow-up data.

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 MRI 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 MRI 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 unilateral 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, it is only 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 11 sources, which was discussed by the committee. The evidence included 1 systematic review, 1 randomised controlled trial (2 publications providing 1- and 2-year follow-up data), 2 non-randomised comparative studies and 6 case series, and is presented in [table 2 of the interventional procedures overview](#). Other relevant literature is in the appendix 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 committee noted that essential tremor can have major consequences on the quality of life for many people.
- 3.6 This procedure is an alternative to more invasive methods used to lesion the thalamus. The lesion produced is permanent.
- 3.7 While this procedure does not preclude subsequent treatments for essential tremor (such as deep brain stimulation), the effects on those subsequent treatments are unknown.
- 3.8 There is a comprehensive training programme offered by the company manufacturing the device used in this procedure.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).