

MRI-guided focused ultrasound thalamotomy for treating moderate to severe tremor in Parkinson's

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 More research is needed on MRI-guided focused ultrasound thalamotomy for treating moderate to severe tremor in Parkinson's before it can be used in the NHS.
- 1.2 This procedure should only be done as part of a formal research study and a research ethics committee needs to have approved its use.

What research is needed

- 1.3 More research is needed on:
 - patient selection (including the severity of Parkinson's and impact of tremor)
 - the technique used
 - safety outcomes
 - longer-term efficacy outcomes.
- 1.4 Patient selection should be done by a movement disorders multidisciplinary team experienced in managing the condition. The procedure should only be done by a multidisciplinary team including a neurosurgeon with specialist expertise in the procedure.

Why the committee made these recommendations

There is little good-quality evidence for this procedure. The evidence is mainly from observational studies and suggests that people who have the procedure have fewer and less severe tremors. A potential benefit is that the tremor reduction can be seen and controlled during the procedure. Some people who cannot have deep brain stimulation may particularly benefit from this procedure. But more evidence is needed.

There are reports of complications and long-term research with more people is needed to understand the longer-term outcomes of the procedure. So it can only be used in research.

2 The condition, current treatments, unmet need and procedure

The condition

2.1 Parkinson's is a progressive neurodegenerative condition that damages the brain over many years. It is caused by a loss of the cells in the brain that produce dopamine, which helps to control and coordinate body movements. People with Parkinson's classically present with the symptoms and signs described as 'parkinsonism': these include bradykinesia (slow movements), rigidity, rest tremor (shaking) and postural instability (loss of balance). In later stages of Parkinson's, other symptoms sometimes described as the 'non-motor' manifestations of Parkinson's such as depression, cognitive impairment, dementia and autonomic disturbances may be prominent. The condition may progress to cause significant impairments, adversely affecting quality of life and, indirectly, the quality of life of family and carers.

Current treatments

2.2 For people with early Parkinson's, drug treatments such as levodopa, other dopamine agonists and monoamine oxidase B inhibitors may be considered. In the later stages, other drugs may be used with levodopa (as adjuvants) to reduce

the motor complications associated with prolonged levodopa use. Non-pharmacological management such as physiotherapy, occupational therapy and speech and language therapy may be considered. Invasive surgical procedures may be considered for people with Parkinson's that is refractory to medical and supportive therapies. These include deep brain stimulation and, less commonly, radiofrequency thalamotomy. Treatments for non-motor symptoms such as sleep disturbance and depression may also be considered.

Unmet need

- 2.3 MRI-guided focused ultrasound thalamotomy is a minimally invasive procedure that may benefit a subgroup of people who do not want the risks of more invasive brain surgery (that is, deep brain stimulation or radiofrequency thalamotomy), or when brain surgery is not an option, especially in older and more frail people.

The procedure

- 2.4 This outpatient procedure is done with the patient lying supine inside an MRI scanner for several hours. The person's head is shaved, and a stereotactic head frame is attached. The person is usually kept awake during the procedure so they can be regularly assessed by the treating physician to evaluate the clinical response (report any improvement of symptoms or adverse events). Some people may be offered light sedation.
- 2.5 Real-time MRI guidance and thermal mapping are used to identify the target area of the brain (the thalamic nucleus) precisely, and monitor treatment. Low-power ultrasound is delivered to confirm the chosen location. Then, several high-power focused ultrasound pulses are delivered to ablate target tissue in the thalamus. The energy released and the location of the ultrasound focus are monitored in real time during the procedure by MRI thermometry, and adjusted to reach above the definitive ablation temperature (of 55°C) according to clinical response. 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 is considered finished when there is sufficient clinical improvement,

considering the total amount of energy delivered and the number of sonications. The procedure takes about 2 hours and symptom relief should be immediate.

3 Committee considerations

The evidence

- 3.1 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 9 sources, which was discussed by the committee. The evidence included 6 case series, 1 randomised controlled trial (reported in 2 papers) and 1 systematic review. It is presented in the [summary of key evidence section in the interventional procedures overview](#). Other relevant literature is in the appendix of the overview.
- 3.2 The professional experts and the committee considered the key efficacy outcomes to be: reduction in tremor, quality of life, use of antiparkinsonian medicine and recurrence of tremor.
- 3.3 The professional experts and the committee considered the key safety outcomes to be: head discomfort or pain, vestibular symptoms (dizziness or vertigo), paraesthesia or numbness, taste, gait disturbance, hand ataxia, dysarthria, asthenia and vocal change.
- 3.4 Patient commentary was sought but none was received.

Committee comments

- 3.5 This procedure has the potential to eliminate tremor in people with Parkinson's, which could have a significant benefit for activities of daily living.
- 3.6 The committee noted the ability to control the position and size of the lesion in real time.

- 3.7 The committee noted that this procedure is used for treating tremor but does not treat other components of Parkinson's. Only a small proportion of people with Parkinson's have tremor as the dominant feature.
- 3.8 The procedure is done unilaterally rather than as a bilateral treatment for safety reasons.
- 3.9 A prospective data collection registry would be useful, particularly for capturing longer-term safety outcomes.

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Endorsing organisation

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