

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

MRI-guided focused ultrasound subthalamotomy for treating Parkinson's

Parkinson's is a condition that damages the brain over many years. It causes progressive symptoms including tremor. MRI-guided focused ultrasound subthalamotomy is a minimally invasive procedure that is done inside an MRI scanner. The person's head is shaved and a frame attached to keep it still. Then high-power focused ultrasound pulses are delivered to destroy tissue in an area of the brain called the subthalamus (subthalamotomy). The aim is to reduce Parkinson's symptoms.

NICE is looking at MRI-guided focused ultrasound subthalamotomy for treating Parkinson's.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts with knowledge of the procedure.

This document contains the [draft guidance for consultation](#). Your views are welcome, particularly:

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

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance
- prepare a second draft, which will go through a [resolution process](#) before the final guidance is agreed.

MRI-guided focused ultrasound subthalamotomy for Parkinson's July 2024

Please note that we reserve the right to summarise and edit comments received during consultation 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: 21 August 2024

Target date for publication of guidance: December 2024

1 Draft recommendations

- 1.1 More research is needed on MRI-guided focused ultrasound subthalamotomy for treating 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.

More research

- 1.3 More research in the form of suitably-powered randomised controlled trials, prospective cohort studies and safety data from a registry is needed on:
- patient selection, including severity of condition and symptoms
 - the site of the lesion
 - the technique used
 - long-term outcomes
 - safety outcomes.

Why the committee made these recommendations

There is very little evidence on the efficacy and safety of this procedure, including only 1 small randomised controlled trial. The evidence suggests the procedure may reduce Parkinson's symptoms including tremor. But the evidence is short-term and comes mainly from only 1 centre. So, the benefits of this procedure are unclear.

The evidence is mostly for advanced Parkinson's in people who had not had symptoms for long. They were also younger than most people with Parkinson's having treatment in the NHS. So, it is unclear who might benefit from this procedure.

This procedure also has the potential for serious complications. So, it can only be used in research.

2 The condition, current treatments 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 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.

The procedure

- 2.3 MRI-guided focused ultrasound subthalamotomy is a minimally invasive procedure that aims to treat some of the symptoms of Parkinson's.
- 2.4 This outpatient procedure is done with the patient lying supine inside an MRI scanner for several hours. The patient'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 (any improvement in symptoms or adverse events). Some people may be offered light sedation.

Real-time MRI guidance and thermal mapping are used to identify and adjust the target area of the brain (the subthalamic nucleus) precisely and continuously monitor treatment. Low-power ultrasound is delivered to confirm the location. Then, several high-power focused ultrasound pulses are delivered to ablate tissue in the subthalamic nucleus (in the dorsolateral motor region and above, and mediodorsally to affect the pallidothalamic tract). 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 4 sources, which was discussed by the committee. The evidence included 1 RCT and 3 prospective studies. 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: improvement in motor features, functional improvement in activities of daily living, reduction in the use of antiparkinsonian medicine, quality of life and patient satisfaction.
- 3.3 The professional experts and the committee considered the key safety outcomes to be: speech problems, gait problems, new onset dyskinesia, facial asymmetry, pins and needles, and weakness on the treated side.
- 3.4 Patient commentary was sought but none was received.

Committee comments

- 3.5 The procedure is used to treat unilateral symptoms of Parkinson's.
- 3.6 Targeting the subthalamic nucleus is designed to treat motor symptoms of Parkinson's including tremor. But a high incidence of undesirable neurological side effects, which may be permanent, have been reported in the literature.
- 3.7 The procedure may have an advantage over surgical and other minimally invasive procedures because it can create a more controlled lesion with real-time monitoring and testing.

- 3.8 The procedure may have a role when a more invasive procedure, such as deep brain stimulation of the subthalamic nucleus, is indicated but is not suitable.

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Chair, interventional procedures advisory committee

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