

Interventional procedures consultation document
MRI-guided laser interstitial thermal therapy
for drug-resistant epilepsy

Epilepsy causes seizures and other symptoms due to abnormal electrical activity in the brain. Patients whose epilepsy does not respond to medications (drug-resistant epilepsy) have other treatment options to control seizures. In this procedure, a small hole is made in the skull and a laser is inserted into the area of the brain (interstitial) causing the seizures. The laser heats up and destroys this area. MRI scanning is used during the procedure to make sure the laser is put in the correct place and to monitor the treatment. The aim is to destroy the part of the brain that is causing seizures.

NICE is looking at MRI-guided laser interstitial thermal therapy for drug-resistant epilepsy.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts, who are consultants 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This document contains the draft guidance for [consultation](#).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 The draft guidance may change after this consultation.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- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance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.

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 November 2019

Target date for publication of guidance: February 2020

1 Draft recommendations

- 1.1 Evidence on the safety of MRI-guided laser interstitial thermal therapy for drug-resistant epilepsy shows there are serious but well recognised safety concerns. Evidence on its efficacy is limited in quality. Therefore, this procedure should only be used with [special arrangements](#) for clinical governance, consent, and audit or research.
- 1.2 Clinicians wishing to do MRI-guided laser interstitial thermal therapy for drug-resistant epilepsy should:
- Inform the clinical governance leads in their NHS trusts.
 - Give patients and their parents or carers clear written information to support [shared decision making](#), including NICE's [information for the public](#).
 - Ensure that patients and their parents or carers understand the procedure's safety and efficacy, as well as any uncertainties about these.
 - Audit and review clinical outcomes of all patients having the procedure. NICE has identified relevant audit criteria and is developing an audit tool (which is for use at local discretion), which will be available when the guidance is published.

- 1.3 Patient selection should be done by a multidisciplinary team experienced in managing drug-resistant epilepsy. This may include a neurologist, neurosurgeon, neurophysiologist, neuroradiologist and psychiatrist.
- 1.4 Further research could be in the form of randomised controlled trials, large case series or collaborative registries. It should report details of patient selection, including the size and site of the lesions being created, patient-reported outcomes and long-term follow up, particularly neurodevelopmental outcomes in children.

2 The condition, current treatments and procedure

The condition

- 2.1 Epilepsy is a neurological condition characterised by episodes of abnormal electrical activity in the brain (recurrent seizures). The seizures can be focal or generalised.

Current treatments

- 2.2 The main treatment for epilepsy is anti-epileptic drugs taken to prevent or reduce the occurrence of seizures. However, many people with epilepsy have drug-resistant epilepsy, which is refractory to medical treatment (estimates vary between 20% and 40% of people with epilepsy). They experience frequent seizures and are at risk of status epilepticus and sudden unexpected death in epilepsy. If medical therapy fails to control the epilepsy adequately, surgery may be considered. Surgical options include open surgical resection (such as lesionectomy, anterior temporal lobectomy or hemispherectomy) or disconnection (such as multiple subpial transection or corpus callosotomy), neuroablation (for example, with stereotactic radiosurgery, radiofrequency thermocoagulation or MRI-guided focused ultrasound) or

neuromodulation (such as cranial nerve stimulation, deep-brain stimulation or closed-loop stimulation).

The procedure

2.3 Preoperatively, an MRI scan is done to identify the part of the brain causing the seizures and to identify the entry location for the laser catheter. The procedure is usually done under general anaesthesia with the patient lying on an MRI couch. A small burr hole is made in the skull and a fine fiberoptic laser catheter is inserted into the target area under stereotactic guidance. Continuous real-time MRI scanning is done to allow visualisation of the exact target area to be ablated and the surrounding tissue, and to monitor the temperature in the brain during the procedure. Under computer guidance, laser energy is applied to the target area. The laser is switched off and removed when temperatures have reached levels sufficient to cause coagulation necrosis (usually 46°C to 60°C) and the target tissue has been ablated. After the procedure, an MRI is done to verify the location and volume of the tissue ablated. The aim is to precisely ablate the target tissue and to minimise damage to the surrounding area. MRI-guided laser interstitial thermal therapy has most commonly been used for patients with a well-defined epileptogenic focus, especially in the temporal lobe, but it can be used elsewhere in the brain.

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 6 sources, which was discussed by the committee. The evidence included 2 meta-analyses, 2 reviews and 2 case reports. It is

presented in table 2 of 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: frequency and severity of seizures, reduction in anti-epileptic medication, reduction in the need for further surgery and quality of life.
- 3.3 The professional experts and the committee considered the key safety outcomes to be: damage to adjacent structures, intracranial/cerebral haemorrhage, cranial nerve/neurologic deficit, gait disturbance, visual field deficits, cognitive deficit or psychiatric disturbance, and amnesic disorder.
- 3.4 Patient commentary was sought but none was received.

Committee comments

- 3.5 The committee noted that, in adults, the procedure has primarily been used to treat temporal lobe epilepsy.
- 3.6 The committee was informed that the procedure is much less invasive than open surgery.
- 3.7 The committee was advised that, in the future, this procedure may be offered as an alternative to drug treatment for epilepsy.

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Chair, interventional procedures advisory committee

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