Patient Support FAQ

Frequently asked questions around Magnetic Resonance-guided Focused Ultrasound (MRgFUS) treatment of Essential Tremor

What is MRgFUS?

MRgFUS, or Magnetic Resonance-guided Focused Ultrasound, is an incisionless procedure requiring no permanent implants for the treatment of Essential Tremor.

How does MRgFUS work?

MRgFUS uses sound waves (ultrasound) guided by MRI to treat Essential Tremor with no incisions or permanent implant.

The ultrasound waves are focused on a small spot in the brain, the Vim of the Thalamus, considered to be responsible for the tremor. The temperature at the target site rises high enough to create a small ablation or burn, providing a therapeutic effect. The MRI is the eyes of the procedure, enabling the treatment team to plan, guide and target the area for treatment. It also acts as a thermometer, providing continuous temperature monitoring in the focus and surrounding area to avoid unintended heating of the surrounding tissue.

Who is suitable for treatment with MRgFUS?

MRgFUS may be a suitable treatment option for patients with moderate to severe Essential Tremor, who do not respond to medications or cannot tolerate them.

In 2023, the procedure was additionally approved for the staged bilateral treatment of Essential Tremor – and therefore in some cases patients who have had one side treated may be able to have the second side treated after discussion with their treating doctor.

Is a person conscious during the MRgFUS procedure?

A person is awake and fully conscious during the MRgFUS procedure. This is important so that the patient can provide feedback on improvement of the tremor and any possible side effects that might occur.

How long does the procedure take?

The MRgFUS procedure is usually performed in an MRI Scanner without sedation and takes approximately 2 hours.

To what extent will the tremor be decreased in the treated arm?

The extent of improvement in the tremor in the treated arm can vary between individuals.

More than 15,000 patients have been treated worldwide. The outcomes of an Insightec sponsored clinical trial demonstrated 73% sustained tremor improvement at 5 years.¹

How quickly does a person respond to the treatment?

Many patients experience an immediate reduction in their tremor. However, ability to regain skills such as writing, picking

up a cup, using cutlery, doing up buttons and zips, using a phone or computer etc., may take longer.

The treatment team will provide you with instructions related to your post-treatment recovery.

What does the MRgFUS procedure involve?

The Focused Ultrasound treatment requires the patient to have a cleanly shaved head. The ultrasound waves will be transmitted into the brain from a helmet-like transducer. This is to ensure there is no interference of the sound waves. A local numbing medication will be applied, and a head frame secured so that your head does not move during treatment.

Your heart rate, blood pressure and oxygen levels will be monitored throughout the treatment. You will be awake, communicating with the treatment team throughout the treatment. You may be given additional medication to keep you comfortable.

Cool water will circulate in the helmet around the top of your head, and you will be kept warm. You will also be given a "stop sonication" button to indicate to the treatment team that you want to stop the treatment for any reason.

Is MRgFUS safe? What side effects might occur?

Overall, the Focused Ultrasound treatment has been shown to be safe for treating Essential Tremor with minimal risk, but as with any medical procedure, there are risks. You should have a detailed conversation with your treatment team regarding complications, also known as adverse events, that you may experience.

An Insightec sponsored clinical study² has shown the most common adverse events after treatment to be:

- Imbalance/gait disturbance (26%)
- Numbness/tingling (33%)
- Headache/head pain (51%)

Most of these events were classified as mild or moderate and 48% of all adverse events resolved on their own within 30 days. Additional infrequent events include dizziness, taste disturbance, slurred speech, fatigue, and vomiting.

Adverse events recorded at a 5-year follow-up1:

- No new adverse events recorded at 5-year follow-up
- No new or worsening of adverse events recorded 1 year after treatment or 5-year follow-up

How long will I need to stay in hospital?

Patients who have had MRgFUS can usually return home the same or the following day.

Is MRgFUS available on the NHS?

Yes. MRgFUS is available within NHS England for the treatment of medication refractory Essential Tremor.

There are currently four centres in the UK established to treat patients with Essential Tremor with MRgFUS, including two NHS hospitals: St Mary's Hospital, Imperial College Healthcare NHS Trust, and The Walton Centre NHS Foundation Trust in Liverpool.

MRgFUS is available on a case-by-case basis on the NHS in Scotland at the University of Dundee.

MRgFUS is also available privately at each of these three centres as well as at the Queen Square Imaging Centre in London, where the MRgFUS Team of the National Hospital for Neurology and Neurosurgery are based.

Am I eligible for MRgFUS treatment?

As part of the evaluation process, the severity of your tremor and your overall health will be evaluated. Patients will need to undergo a CT scan to determine suitability.

Any metallic implants must be MRI-compatible to prevent injury from the MRI's magnetic field.

If you are not generally healthy enough to withstand the treatment and lie in the same position for over 2 hours, you may not be a suitable candidate for this treatment.

There are additional limitations, the treatment team will perform an assessment to verify suitability for the treatment.

How would I find out if I am suitable?

An assessment of your suitability for therapy will ultimately need to be carried out by the team performing the MRgFUS. **Step 1:** As a first step, you should ask your GP to refer you to a movement disorder neurologist at one of the listed hospitals for an initial assessment.

Step 2: Your neurologist should be able to establish or confirm the diagnosis of Essential Tremor and this will start a discussion about the management of your tremor, including possible medical options, deep brain stimulation (DBS) and/or MRgFUS.

Step 3: If suitable, your neurologist can refer you for treatment. Prior to the appointment, note down the questions you would like to ask, you may even wish to print and take with you information about MRgFUS from this website.

Contact details of the four centres Ninewells Hospital, The University of Dundee, Scotland tgilbertson@dundee.ac.uk

Queen Square Imaging Centre, The National Hospital for Neurology and Neurosurgery, London www.queensquare.com/services/focused-ultrasound-essential-tremor-treatment/ 020 7833 2513

St Mary's Hospital, Imperial College Healthcare NHS Trust, London imperial.mrgfusenguiries@nhs.net

The Walton Centre NHS Foundation Trust, Liverpool www.thewaltoncentre.nhs.uk/departments-and-services/essential-tremor-ultrasound-thalamotomy/604532 wcnnreferrals@nhs.net 0151 556 3351

For healthcare professionals, please click here for more information.

References

Cosgrove GR, Lipsman N, Lozano AM, et al. Magnetic resonance imaging-guided focused ultrasound thalamotomy for essential tremor: 5-year follow-up results.
Pre-Market Approval (PMA) P150038: <u>https://www.accessdata.fda.gov/cdrh_docs/pdf15/P150038B.pdf</u>