



DOSSIER · THERAPY

Focused Ultrasound Therapy

Focused ultrasound therapy is a non-invasive procedure that directs high-intensity ultrasound energy at targeted tissue. The method is primarily studied in neurology, with a substantial proportion of the research being observational — controlled data remain limited for many applications.

427

STUDIES IN
TOTAL

345

IN HUMANS

22

OF WHICH
CONTROLLED

2

IN ANIMALS

2

IN THE LAB

Figures from the IHR study database · Last updated 2026-10-15

How to Read This Dossier

ESTABLISHED

measured in humans, with a comparison group

PLAUSIBLE

supported by mechanism, animal studies or observation

HYPOTHESIS

a likely connection that still needs to be tested

Focused ultrasound therapy at a glance

ORIGIN:

Focused ultrasound therapy (MRgFUS) is a non-invasive procedure that directs focused ultrasound waves under real-time MRI guidance with millimetre precision to target tissues. Originally developed in the 1950s for tumour ablation, it was only the combination with MRI in the 2000s that enabled safe application in the brain. Today, it is primarily used in neurology to treat tremor, Parkinson's disease and neuropathic pain without requiring incisions or implants.

EVIDENCE BASE:

427 studies reviewed · 22 controlled human studies · 323 observational studies · 17 review articles · 2 animal studies · 2 cell culture studies

STRONGEST EVIDENCE:

- **Movement disorders (Essential tremor/Parkinson's disease) Proven:** Randomised controlled trials demonstrate significant and sustained tremor reduction (CRST from 40.7 to 9.3 after 1 month) and stable motor improvements (UPDRS) over 2 years following MRgFUS thalamotomy. Adverse effects such as gait instability were transient, and direct comparisons with deep brain stimulation (DBS) confirm comparable efficacy with different risk profiles.
- **Oncology: (Glioblastoma) Plausible:** A feasibility study (2014) first demonstrated safe partial tumour ablation in recurrent glioblastoma without neurological deficits. The method proved technically feasible, though long-term tumour control and scalability to larger patient groups remain unaddressed.
- **Neuropathic pain Plausible:** A systematic review (2023) of 66 patients showed variable pain reduction (VAS) after bilateral MRgFUS thalamotomy, with rare transient adverse effects. A phase I study confirmed safety but emphasised the need for larger RCTs with standardised pain scales.
- **Blood-brain barrier (Neurodegeneration) Plausible:** A feasibility study in 4 ALS patients confirmed safe transient opening of the blood-brain barrier via MRgFUS without severe adverse effects. The method may enable targeted drug delivery, though clinical efficacy remains unproven.

LIMITATIONS:

- **Long-term safety** Data on late sequelae such as cognitive changes or secondary dystonia are lacking, as follow-up periods typically do not exceed 2 years. Bilateral procedures remain insufficiently investigated.
- **Patient selection** Efficiency of energy transmission depends on skull morphology (SDR), limiting applicability. Direct comparisons with DBS are rare and confined to small cohorts.
- **Heterogeneous target regions** Studies employ different target structures (e.g., VIM, pallidum, central lateral nucleus), complicating comparability of results. Standardised protocols are lacking.

ASSESSMENT:

Focused ultrasound therapy (MRgFUS) is a non-invasive procedure with proven efficacy in movement disorders such as essential tremor and Parkinson's disease, distinguished by real-time MRI guidance and the absence of implants, while questions regarding long-term safety and standardisation remain open.

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1. What Focused Ultrasound Therapy Is

Focused **ultrasound therapy** (MRgFUS, Magnetic Resonance-guided Focused Ultrasound) uses focused ultrasound waves to precisely heat or mechanically influence tissue. The procedure is performed under real-time imaging (primarily MRI) to reach target structures with millimetre accuracy. Originally developed for tumour ablation, it is now mainly used in neurology, for example to treat **tremor** or **Parkinson's symptoms**. The technology dates back to the 1950s, but it was only the combination with MRI in the 2000s that enabled safe application in the brain.

The decisive advantage of the method lies in its **non-invasiveness**: unlike surgical interventions or radiotherapy, it requires no incisions or implants. The ultrasound waves penetrate the skull and exert their effect only at the focal point, where temperatures of up to 60 °C can be reached. This enables targeted lesions in deep brain structures such as the **thalamus** or **pallidum** without damaging surrounding tissue. Real-time temperature monitoring via MRI minimises risks and allows for individualised treatment.

2. What the Studies Show in Detail

The key human studies and most important reviews — grouped by application area, with population, duration, preparation, measurement and outcome as reported in the original studies. Numbers are included only where the study provides them.

Distribution of **controlled human studies** by application area — the numbers are not summable as a single study may be assigned to multiple areas:

APPLICATION AREA	CONTROLLED STUDIES
Safety and tolerability	17
Skin	2
Musculoskeletal system	2
Oncology	2

APPLICATION AREA	CONTROLLED STUDIES
Gut and microbiome	2
Immune system	1
Cognition and psyche	1

Oncology: Glioblastoma Ablation

PROVEN The first clinical feasibility study on magnetic resonance-guided focused ultrasound therapy (MRgFUS) for brain tumours examined a 63-year-old patient with a centrally located recurrent glioblastoma in 2014. Under MRI guidance, 25 high-intensity sonications were applied, resulting in partial tumour ablation. The patient exhibited no neurological deficits or other adverse effects, confirming the safety and technical feasibility of the method. The study demonstrated for the first time that MRgFUS can ablate substantial volumes of brain tumour tissue without invasive procedures ¹.

HYPOTHESIS The precise control of thermal ablation via MRgFUS could potentially address a therapeutic gap, particularly in inoperable or recurrent glioblastomas. However, as the study included only a single case, it remains unclear whether the findings are applicable to larger patient populations. Furthermore, data on long-term tumour control and overall survival are lacking. The next step would involve multicentre phase II trials with standardised ablation protocols and extended follow-up periods to assess oncological efficacy.

Movement Disorders: Essential Tremor and Parkinson's Disease

PROVEN A 2018 study involving 30 patients (18 with essential tremor [ET], 9 with Parkinson's disease [PD], and 3 with ET-PD) examined the safety and efficacy of MRgFUS thalamotomy of the ventral intermediate nucleus (VIM). The procedure resulted in immediate cessation of tremor in the treated hand. After one month, the *Clinical Rating Scale for Tremor* (CRST) improved in ET patients from 40.7 ± 11.6 to 9.3 ± 7.1 ($p < 0.001$) and remained stable after six months (8.2 ± 5.0). PD patients showed a comparable reduction in motor UPDRS scores. Adverse effects were mild and transient, including temporary gait instability and paraesthesia ².

PROVEN A follow-up study with 76 ET patients confirmed the sustained efficacy of MRgFUS thalamotomy over two years. Nine patients withdrew early (e.g., due to alternative therapies), but results remained stable in all analysed participants. The study highlights the durability of tremor control but notes the need for long-term data beyond five years to assess late complications such as cognitive changes or secondary dystonia.

PROVEN A direct comparison between MRgFUS thalamotomy and deep brain stimulation (DBS) in ET showed that both methods significantly reduced tremor and improved quality of life. MRgFUS was associated with higher rates of persistent neurological side effects (e.g., sensory disturbances), while DBS more frequently presented surgery- or hardware-related complications (e.g., intracranial haemorrhage). The study emphasises that the choice of procedure depends on individual risk profiles and that MRgFUS represents a valid alternative for patients with contraindications to invasive interventions.

PROVEN A meta-analysis of three randomised controlled trials (RCTs) involving 161 PD patients (115 with MRgFUS) assessed the safety of MRgFUS pallidotomy. The most common side effects were dizziness (odds ratio [OR] 4.25) and gait-related disturbances (OR 4.53), while life-threatening events did not occur significantly more often than in the sham group. The study confirms an acceptable safety profile but highlights the need to consider patient-specific factors such as skull volume and density (SDR), which influence energy transmission efficiency.

Neuropathic Pain

PROVEN A 2023 systematic review analysed three observational studies involving a total of 66 patients (with neuropathic pain [NP] or trigeminal neuralgia) who underwent bilateral MRgFUS thalamotomy of the central lateral nucleus. Pain intensity, measured using the visual analogue scale (VAS), showed variable improvement, with effects persisting over different follow-up periods. Side effects were rare and transient (e.g., dizziness, paraesthesia), with a single severe complication (intracerebral haemorrhage). The study underscores the potential of MRgFUS for therapy-refractory NP but notes the heterogeneity of target regions and outcome measures ³.

PROVEN A phase I study involving ten NP patients (phantom limb pain, spinal cord injury, radiculopathy) examined the safety and efficacy of MRgFUS central lateral thalamotomy. No severe adverse events occurred, but the study stresses the need for larger RCTs with standardised pain scales and longer follow-up periods to validate efficacy ⁴.

Focal Hand Dystonia

PLAUSIBLE An ongoing open-label study is investigating MRgFUS thalamotomy of the Vo complex in ten patients with focal hand dystonia. The study combines clinical, kinematic, neurophysiological, and imaging methods to evaluate efficacy and potential motor costs. The aim is to test the hypothesis that neuroplastic and structural changes may explain treatment success. Preliminary pilot data suggest efficacy, but the study is still in its early stages, and controlled data on long-term safety and comparison with established therapies such as botulinum toxin are lacking ⁵.

Gynaecological and Dermatological Applications

PROVEN A randomised phase II study involving 76 female patients (45 with squamous hyperplasia, 31 with lichen sclerosus) examined the efficacy of focused ultrasound in vulvar dystrophies. At two-year follow-up, 49 patients were cured, 23 improved, and 4 remained unchanged. The expression of CD34 and myelin basic protein (MBP) increased significantly ($p < 0.05$), indicating regeneration of the skin barrier. The study demonstrates that focused ultrasound may represent a non-invasive alternative to surgical or pharmacological therapies, though comparative studies with standard treatments such as topical steroids are still needed.

Focused ultrasound was associated with a reduced risk of vaginal bleeding (RR = 0.09) and discharge (RR = 0.10) and an increased cure rate (RR = 1.10) and overall effectiveness (RR = 1.04) in the included observational studies. The recurrence rate was also lower (RR = 0.13, $p = 0.05$). The review highlighted advantages in safety and efficacy but noted the high risk of bias in the included studies, necessitating confirmation through high-quality RCTs.

ENT: Inferior Turbinate Hypertrophy

PROVEN A randomised controlled study involving 20 patients compared high-intensity focused ultrasound (HIFU) with coblation for inferior turbinate hypertrophy. Both methods led to significant improvement in nasal breathing (NOSE score and NO-VAS), with HIFU showing faster resolution of mucosal swelling and less crusting. Pain intensity during the procedure was lower with HIFU (4.9 vs. 6.3, $p = 0.143$), though not significantly. The study suggests comparable efficacy, with advantages for HIFU in terms of mucosal preservation and comfort. However, long-term data on recurrence rates and structural integrity of the turbinates are still lacking ⁶.

Blood-Brain Barrier and Neurodegenerative Diseases

PLAUSIBLE A first-in-human feasibility study involving four ALS patients examined the safety of MRgFUS for transient opening of the blood-brain barrier (BBB) in the primary motor cortex. BBB opening was confirmed by gadolinium leakage immediately after sonication and normalised after 24 hours. No severe adverse events occurred, and the method proved safe and feasible. The study lays the groundwork for future applications of MRgFUS for targeted drug delivery in neurodegenerative diseases, though clinical efficacy in humans is not yet investigated, and preclinical findings on BBB modulation remain to be validated in larger cohorts ⁹.

HYPOTHESIS Combining MRgFUS with cell-based therapies (e.g., stem cells or immune cells) could open new avenues for treating neurodegenerative diseases such as Alzheimer's or Parkinson's. Preclinical data suggest that MRgFUS enhances the migration and integration of therapeutic cells into the brain. However, clinical studies in humans are still lacking to confirm this hypothesis. The next step would be phase I trials using standardised cell therapies and MRgFUS protocols to evaluate safety and feasibility ¹².

Overall Picture

Over the past decade, focused ultrasound therapy (MRgFUS) has emerged as a promising non-invasive alternative to established neurosurgical procedures. The most robust data exist for the treatment of movement disorders, particularly essential tremor and Parkinson's disease, where randomised controlled trials showed significant and sustained symptom improvement with an acceptable safety profile. In these indications, the method demonstrates comparable efficacy to deep brain stimulation, with the advantage of incisionless procedures and real-time control of ablation. In oncology and pain therapy, research is still in its infancy, but early feasibility studies indicate high potential, particularly for patients with contraindications to invasive interventions.

Outside the CNS, MRgFUS has already found clinical application in gynaecology and dermatology, with promising results in vulvar dystrophies and cervical ectopy. However, the evidence base here is more heterogeneous, and direct comparisons with standard therapies are lacking. In ENT and neurodegenerative diseases, applications remain experimental, but the ability to transiently open the blood-brain barrier could revolutionise the treatment of previously incurable conditions. Systematic gaps remain, particularly in long-term follow-up, standardisation of protocols, and identification of predictors for treatment response.

Methodology of the evidence base

[‘Studies on focused ultrasound therapy encompass a wide range of designs, from case reports and phase I trials to randomised controlled trials (RCTs) and meta-analyses. Typical endpoints include clinical scales (e.g., CRST, UPDRS, VAS), imaging methods (MRI for ablation control), and safety parameters (adverse events, complications). Follow-up periods vary widely, from a few months in feasibility studies to two years in long-term studies. Systematic weaknesses include heterogeneity of target regions (e.g., VIM, pallidum, central lateral nucleus), lack of blinding in many studies, and limited patient numbers, particularly in oncological and pain-related applications. Additionally, direct comparisons with established therapies (e.g., DBS, radiosurgery) and data on patient-specific factors such as skull morphology, which influence energy transmission efficiency, are often missing. The next step would be multicentre RCTs with standardised protocols and longer follow-up periods to validate efficacy and safety across all applications.’]

Thalamotomy: Revolution or niche procedure?

Focused ultrasound

THALAMOTOMY

is considered a promising alternative to deep brain stimulation (DBS) for **essential tremor** and **Parkinson's disease**. Controlled studies show a **significant reduction in tremor**, but direct comparisons with DBS are rare, and sample sizes are limited. It remains unclear whether the effects are durable or whether **late complications** such as cognitive decline may occur. A meta-analysis confirms efficacy but highlights **heterogeneous results**, for example regarding the safety of bilateral procedures.

Another challenge is

PATIENT SELECTION

: the method is not suitable for all individuals, as skull structure affects ultrasound wave transmission. Studies show that in some candidates, the **skull is too dense** to transmit sufficient energy. It is also unclear whether MRgFUS is as effective in **advanced Parkinson's disease** as it is in tremor. **Oncological applications** (e.g., liver tumours) remain experimental and are based on small case series—here, controlled data on superiority over established procedures such as radiofrequency ablation are still lacking.

3. How Robust the Research Is

Research on focused ultrasound therapy focuses on **neurological diseases**, particularly **essential tremor** and **Parkinson's disease**. While observational studies form the majority of the evidence base, a subset of controlled trials addresses areas such as **safety**, **skin**, **musculoskeletal system**, **oncology**, **gut**, **immune system**, and **cognition**. The most frequently cited controlled studies examine **thalamotomy** for tremor and Parkinson's, including meta-analyses and long-term data.

Methodologically, the field is dominated by **observational studies** that demonstrate safety and feasibility but do not allow causal conclusions. The available controlled studies are often small and unblinded, limiting their conclusiveness. Direct comparisons with established procedures such as **deep brain stimulation (DBS)** in larger cohorts are also lacking. **Review articles** highlight the method's potential but point to unresolved questions—such as **long-term safety** or **optimising targeting accuracy** across varying skull structures.

4. Common Claims — and What the Data Support

CLAIM	EVIDENCE BASE
Pain management	Controlled studies on the treatment of neuropathic pain are available, but the findings are not sufficient to classify the method as a standard procedure.
Psychiatric disorders	Individual studies have examined MRgFUS in depression or obsessive-compulsive disorder , but the evidence remains preliminary. Mechanistic research pred
Blood-brain barrier	The opening of the blood-brain barrier for medications (e.g., in ALS) is being investigated in observational studies, but controlled data on efficacy are still pend
Skin and soft tissue disorders	Controlled studies examine vulvar dystrophies and soft-tissue tumours , yet sample sizes are too small to draw general conclusions.

5. The Most Robust Studies

Ranked by evidence strength, not prominence. The full evaluation includes many more studies; here, the most compelling are listed.

Controlled Human Studies

- ¹ First noninvasive thermal ablation of a brain tumor with MR-guided focused ultrasound (2014)
- ² Magnetic resonance-guided focused ultrasound thalamotomy for tremor: a report of 30 Parkinson's disease and essential tremor cases (2018)
- A prospective trial of magnetic resonance-guided focused ultrasound thalamotomy for essential tremor: Results at the 2-year follow-up (2018)
- A meta-analysis of outcomes and complications of magnetic resonance-guided focused ultrasound in the treatment of essential tremor (2018)
- The efficacy and limits of magnetic resonance-guided focused ultrasound pallidotomy for Parkinson's disease: a Phase I clinical trial (2019)
- Comparison between deep brain stimulation and magnetic resonance-guided focused ultrasound in the treatment of essential tremor: a systematic review ... (2020)
- Unilateral Thalamic Deep Brain Stimulation Versus Focused Ultrasound Thalamotomy for Essential Tremor (2019)
- Focused ultrasound therapy of vulvar dystrophies: a feasibility study (2004)
- Focused ultrasound therapy for movement disorders (2025)
- Magnetic resonance-guided focused ultrasound for the treatment of tremor (2022)
- ³ Magnetic Resonance-guided Focused Ultrasound thalamotomy for refractory neuropathic pain: a systematic review and critical appraisal of current ... (2023)
- ⁴ Focused Ultrasound Central Lateral Thalamotomy for the Treatment of Refractory Neuropathic Pain: Phase I Trial (2024)
- Incisionless MR-guided focused ultrasound: technical considerations and current therapeutic approaches in psychiatric disorders (2020)
- ⁵ Evaluation of the efficacy and safety of MRI-guided focused ultrasound (MRgFUS) for focal hand dystonia: study protocol for an open-label ... (2023)
- Safety of Focused Ultrasound Ablation in Parkinson's Disease: A Meta-Analysis of Randomized Controlled Trials (2025)
- Efficacy and safety of focused ultrasound versus microwave therapy for cervical ectopy: a meta-analysis (2015)
- Magnetic resonance imaging-guided focused ultrasound thalamotomy launch with remote telemedicine international proctorship (2024)
- ⁶ High-Intensity Focused Ultrasound Therapy Versus Coblation for the Treatment of Inferior Turbinate Hypertrophy: A Clinical Trial (2023)
- Effect of low-intensity focused ultrasound therapy on postpartum uterine involution in puerperal women: A randomized controlled trial (2024)
- ⁷ Staged Bilateral Magnetic Resonance-Guided Focused Ultrasound for Treating Essential Tremor: Systematic Review and Meta-Analysis (2026)
- ⁸ Magnetic resonance-guided focused ultrasound for the management of tremor: update on the position statement of the American Society for Stereotactic ... (2026)

Observational Human Studies

- ⁹ First-in-human trial of blood-brain barrier opening in amyotrophic lateral sclerosis using MR-guided focused ultrasound (2019)
- ¹⁰ First experience with MR-guided focused ultrasound in the treatment of Parkinson's disease (2014)
- ¹¹ Focused ultrasound thalamotomy location determines clinical benefits in patients with essential tremor (2018)

6. Summary

What is proven: MRI-guided focused ultrasound therapy (MRgFUS) is best studied for movement disorders such as essential tremor and Parkinson's disease. Randomised controlled trials demonstrate significant and sustained tremor reduction (e.g., CRST reduction from 40.7 to 9.3 after 1 month) and comparable efficacy to deep brain stimulation (DBS), though with different risk profiles. The method is non-invasive, requires no implants, and allows real-time control of ablation via MRI. In oncology (glioblastoma) and pain therapy (neuropathic pain), feasibility studies confirm technical feasibility and safety, but with limited sample sizes and no long-term data.

What is plausible and potential implications: **Hypothesis:** The precise targeting of MRgFUS could address a therapeutic gap in inoperable or recurrent glioblastomas by ablating substantial tumour volumes without invasive procedures. However, data on long-term tumour control and overall survival remain lacking. In pain therapy, MRgFUS shows potential for refractory neuropathic pain, but heterogeneity in target areas and outcome measures complicates evaluation. **Hypothesis:** Combining MRgFUS with cell-based therapies (e.g., stem cells) may open new avenues in treating neurodegenerative diseases such as Alzheimer's or Parkinson's, as preclinical data suggest improved cell migration. Clinical trials in humans are still pending. For ENT (inferior turbinate hypertrophy) and neurodegenerative applications (blood-brain barrier), results are promising but remain experimental.

What remains to be clarified: To establish focused ultrasound therapy as a standard procedure, multicentre randomised controlled trials (RCTs) with longer follow-up periods (>5 years) are needed, particularly to assess long-term safety and identify predictors of response. Direct comparisons with established procedures such as DBS or radiosurgery in larger cohorts would clarify MRgFUS's position in the treatment algorithm. Standardised protocols for target areas (e.g., thalamus, pallidum) and energy delivery must be developed to optimise efficiency across different skull structures. In oncology and pain therapy, phase II studies with larger patient numbers and uniform outcome measures are required to validate clinical efficacy. For neurodegenerative diseases, phase I studies combining MRgFUS with medications or cell therapies could assess feasibility and safety. Finally, systematic collection of patient-specific factors (e.g., skull volume, density) would be critical to expand the applicability of the method.

7. Open Questions

- **Long-term data:** How stable are the effects after several years, particularly in neurological diseases?
- **Comparisons with DBS:** Lack of large, randomised studies directly comparing MRgFUS with deep brain stimulation.
- **Patient selection:** Which skull characteristics or disease stages are optimal for MRgFUS?

Frequently Asked Questions

Can focused ultrasound replace deep brain stimulation?

The evidence base is not yet sufficient to assess MR-guided focused ultrasound (MRgFUS) as an equivalent alternative to deep brain stimulation (DBS). While controlled studies do show **tremor reduction**, direct comparative trials are lacking. Additionally, MRgFUS is not suitable for all patients — for example, those with very dense skulls. The decision depends on individual factors, including disease stage and anatomical conditions.

How safe is the method for brain tumours?

The **non-invasive ablation of brain tumours** has been investigated in controlled studies, but sample sizes remain limited. The method is considered safe for **small, well-defined tumours**, though robust data are lacking for larger or diffusely growing tumours. The **opening of the blood-brain barrier** for chemotherapeutic agents is being explored in observational studies but remains experimental.

What side effects are known?

The most common side effects include **transient headaches**, **skin redness**, or **mild nausea** due to MRI monitoring. In thalamotomies, **balance disturbances** or **sensory disturbances** may occur, typically reversible. Serious complications such as **intracerebral haemorrhage** are rare but possible. **Long-term safety** has not yet been conclusively established.

Sources

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Research, put in context. Every statement leads to the original paper; the decision in the individual case rests with the treating professional.
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