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Parallel transmit for 7T MRI imaging in epilepsy

Submission date
03/06/2024

Recruitment status
No longer recruiting

Registration date
05/06/2024

Overall study status
Ongoing

Last Edited
25/03/2025

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
360,000 people have focal epilepsy in the UK, one-third of whom have persistent seizures despite medication. Persistent seizures make it difficult to work, impossible to drive, and carry a high risk of death. Epilepsy surgery transforms lives by stopping seizures in 70% of patients when there is a clear resection target. Current NHS standard of care uses 3T MRI and FDG-PET brain scans to identify surgical targets, but this combination is often inconclusive. 7T MRI is recommended because of enhanced sensitivity, but there are two practical barriers to clinical implementation:
1. Lesions are often in the temporal lobes (areas of the brain) where conventional (single transmit) 7T MRI is obscured by signal drop-outs.
2. No 7T MRI sequences are CE marked for clinical use in epilepsy.
The consensus group recommend the development of parallel transmit 7T MRI to improve the visualisation of lesions in the temporal lobes where conventional (single transmit) 7T MRI can be obscured by signal drop-outs. This study will evaluate the use of parallel transmit 7T MRI sequences to remove these barriers to 7T MRI in hospitals performing epilepsy surgery, offering patient benefits and cost savings. This will provide proof-of-concept for future industry collaboration to seek CE marking of the scanner hardware and sequences for routine clinical implementation, but the current study has no manufacturer involvement and will not directly lead to commercialisation.

Who can participate?
Patients aged over 18 years with drug-resistant focal epilepsy who are being evaluated for surgery and have normal or equivocal 3T MRI brain imaging

What does the study involve?
Participants will undergo a parallel transmit 7T MRI brain scan.

What are the possible benefits and risks of participating?
The researchers hope that the scan will show more information about where in the brain epilepsy is coming from, allowing surgical decisions to be made more accurately. The main risk is that the scan will provide no additional information and will be a waste of time.

Where is the study run from?
Cambridge University Hospitals (UK)

When is the study starting and how long is it expected to run for?
October 2022 to March 2026

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Dr Thomas E Cope, thomas.cope@nhs.net

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
322922

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 54920, IRAS 322922

Study information

Scientific Title
Parallel transmit for 7T MRI imaging in epilepsy

Study objectives
Does parallel transmit 7T MRI detect lesions better than 3T MRI, and better than single transmit 7T MRI?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/02/2023, Solihull Research Ethics Committee (Equinox House, City Link, East Midlands REC Centre, NG2 4LA, UK; +44 (0)2071048071; solihull.rec@hra.nhs.uk), ref: 23/WM /0008

Study design
Non-randomized; Both; Design type: Diagnosis, Imaging, Validation of investigation /therapeutic procedures

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Epilepsy

Interventions
Suitable patients will be identified by the epilepsy clinical multi-disciplinary team, from the established CUH epilepsy surgery pathway. We anticipate that the primary utility of 7T MRI in these patients will be to detect suspected lesions not detected by a standard clinical MRI, which will usually have been performed on a 3Tesla scanner. Requests for this indication must be made by a consultant neurologist and approved by a consultant neuroradiologist on receipt of the necessary clinical details.

There may also be patients in whom a 7T MRI may be deemed beneficial for other indications. For example, it might allow further characterization of a structural abnormality observed at lower field strength, both in terms of nature and precise extent. This may allow more precise surgical planning or pre-surgical electrode positioning. Requests for any such indication must be approved by the epilepsy multi-disciplinary team, before approval by a consultant neuroradiologist.

The patient will then be approached by the clinical team, who will explain the 'off-label' nature of 7T imaging, and ask them if they would like to attend for this additional scan (which supplements and does not replace usual clinical care).

Only at this stage will the research team be informed of the patient, and then asked to make an appointment for 7T imaging.

The patient will attend their appointment, completing the CUH-approved consent form (attached), as well as the usual WBIC safety questionnaires. They will undergo a single scan, lasting approximately 1 hour.

Clinical images will then be uploaded to CUH PACS, while research images will be anonymised before transfer to the established WBIC imaging database along with patient age and sex.

The clinical team will undertake follow-up and, with the patient's permission, provide the research team with anonymised longitudinal details about the type of epilepsy the patient has, what treatments they receive, and how well they are able to control their seizures both before and after imaging.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Whether the parallel transmit 7T MRI scan changes the epilepsy multi-disciplinary team's management plan: the MDT management plan is recorded before and after review of 7T, and a decision is made on whether it has changed.

Secondary outcome measures
1. Epilepsy surgical outcomes in terms of seizure freedom and quality of life measures, assessed longitudinally after surgery using Engel and ILAE outcome scales and the Quality of Life in Epilepsy Inventory
2. Correlation between 7T MRI and stereotactic EEG and neuropathology findings

Overall study start date
19/10/2022

Completion date
31/03/2026

Eligibility

Key inclusion criteria
1. Age >18 years
2. Drug-resistant focal epilepsy (DRFE), defined as focal epilepsy that remains refractory to treatment with anti-epileptic medication, defined as continuing to have seizures despite adequate trials of two medications over 2 years
3. A desire to have curative surgery (i.e. the patient is in an established epilepsy surgery pathway)
4. A decision by the treating epileptologist that finding a new lesion, or better characterising a lesion poorly visualised at 3T MRI, would make a material difference to patient treatment options

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 35; UK Sample Size: 35

Key exclusion criteria
1. Pregnancy
2. The presence of non-MRI-safe metal implants
3. Implanted medical devices not certified as compatible with ultrahigh-field MRI (e.g.cardiac pacemakers)
4. Lack of mental capacity to consent to study involvement
5. Severe claustrophobia

Date of first enrolment
30/06/2023

Date of final enrolment
31/03/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Addenbrookes (Primary Site)
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Kings College Hospital (PIC Site)
Mapother House
De Crespigny Park

Denmark Hill
London
United Kingdom
SE5 8AB

Study participating centre
University Hospital Birmingham (PIC Site)
Queen Elizabeth Hospital
Edgbaston
Birmingham
United Kingdom
B15 2TH

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust

Sponsor details
Cambridge Biomedical Campus
Hills Road
Cambridge
England
United Kingdom
CB2 0QQ
+44 (0)1223 217418
CUH.research@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://www.cuh.org.uk/

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC); Grant Codes: MR N013433-1

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
31/03/2027

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Prof. Christopher Rodgers (ctr28@cam.ac.uk)

IPD sharing plan summary
Available on request