Value of Ultra High field MRI for lesion detection in patients with suspected focal epilepsy and negative 3T MRI

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Ethical review	Approved WMO
Status	Completed
Health condition type	Seizures (incl subtypes)
Study type	Observational non invasive

Summary

ID

NL-OMON54565

Source
ToetsingOnline

Brief title
U to 3

Condition

- Seizures (incl subtypes)
- Nervous system, skull and spine therapeutic procedures

Synonym
Drug-resistent focal epilepsy; epilepsy

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Epilepsy, Focal, high field MRI

Outcome measures

Primary outcome

Primary endpoint: the proportion of patients in whom apparent structural brain lesions are detected on ultra high field MRI. Postoperative seizure outcome one year after resective epilepsy surgery (Engel/ILAE class).

Secondary outcome

Secondary endpoints:

1. Differences between the ROI as previous determined in the non- or semi-invasive workup, and the contralateral (non-epileptic) side.

2. Association between suspected ROI in the non- or semi-invasive workup and the ultra high field MRI data.

3. Histopathological diagnosis of surgical specimen

4. Differences in ultra high field MRI performed in the same patient

Study description

Background summary

The prevalence of epilepsy is reported to be between 5 to 8 per 1,000 inhabitants, with a cumulative risk of having epilepsy somewhere during life of 3%. Based on seizure type, at least 61% of these patients are suffering from localisation related epilepsies (Browne, 2000). Many patients still have no lesion visible on the conventional MRI (3-Tesla) as a possible cause for their epilepsy. In children with epilepsy this is about one-third (Reijs, 2007). The study hypothesis is that the use of higher field strength MRI-scanners will improve the detection of (small) structural brain lesions in patients with focal drug-resistant epilepsy, potentially resulting in better seizure outcome

after resective epilepsy surgery.

Study objective

The primary purpose of this study is to improve detection rate of (small) structural brain lesions by using ultra high field MRI in patients with focal drug-resistant epilepsy, and to use this information to improve seizure outcome one year after epilepsy surgery (Engel/ILAE class).
Secondary purposes are:
1. to compare suspected regions of interest (ROI) in the suspected hemisphere in the non- or semi-invasive workup to the contralateral side.
2. to assess associations between suspected regions of interest (ROI) in the non- or semi-invasive workup and ultra high field MRI data.
3. to assess associations between ultra high field MRI abnormalities, histopathology and postoperative seizure outcome.
4. comparison of 2 ultra high field MRI*s in the same patient
Separately, a research protocol is prepared to study 9.4T MRI results of in vivo ROI*s in a selected group of patients and compare this with surgically removed lesions.

Study design

prospective, longitudinal, therapeutic study

Study burden and risks

Burden: One visit to the ultra high field-MRI-unit of Scannexus, Maastricht (two visits for 10 patients). 60 Minutes of MRI-acquisition.
Participating in this study can improve surgical intervention and improve chances of seizure outcome/freedom, especially in children.
If abnormalities are found in epilepsy surgery candidates, the information will be passed on to the epilepsy surgery workgroup. The members of this workgroup are aware that at present the obtained information is not validated and therefore should be interpreted with utmost caution. Even if the ultra high field MRI is negative and no focal lesion explaining the epilepsy is found, the information from the MRI is still valuable to both the treatment and science.
The opposing burden of participation in the study is low, and consists only of an extra MRI scan, without any associated risks with the used MRI protocols.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age >=12 years
Drug-resistant focal epilepsy
Work-up for epilepsy surgery
Clear suspicion on the focal onset of the epilepsy
Absent explanatory abnormalities on conventional 3T MRI
Informed consent signed

Exclusion criteria

Incapacitated to sign informed consent
Not mentally competent individuals
Patients and/or legal representative is mentally retarded (IQ < 70)
Pregnant
MRI-exclusion criteria:
Claustrophobia

Pacemaker, neurostimulator, insulin pump or other pump
Aneurysm clips in cerebro
Metal particles in the head (incl. eye)
Hearing prostheses (not all types)
Tattoos above diaphragm
Relative contra-indications (depending on place and kind):
Artificial heart valves
Joint protheses
Overweight (surgery with standard operating table up to 175kg, or obesity making MRI-scanning impossible due to size)
Other body implants that are not proven safe at 7 or 9.4 Tesla MRI

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	07-05-2021
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	7T Magnetom MRI; 9.4T Magnetom MRI
Registration:	No

Ethics review

Approved WMO

Date:	08-05-2019
Application type:	First submission

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	05-02-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	22-06-2023
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 20236
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL66929.068.18