Added value of ultra high field MRI for detection of a cause of epilepsy

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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.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20236

Source
Nationaal Trial Register

Brief title
EpiUltraTesla

Health condition

Epilepsy Focal drug-resistant epilepsy

Sponsors and support

Primary sponsor: Academic hospital Maastricht (azM), Maastricht, The Netherlands
Source(s) of monetary or material Support: No funding is received for this study.

Intervention

Outcome measures

Primary outcome

The presence or absence of apparent structural abnormalities on Ultra high field MR brain

imaging in patients with focal drug-resistant epilepsy.

Secondary outcome

1. Ultra high field MRI differences between the suspected regions of interest (ROI) (blurring cortical-subcortical junction/cortical thickening/transmantle sign/hyperintensity of grey and white matter/abnormal gyral-sulcal pattern/segmental or lobar hypoplasia) as previous determined and the contralateral side in patients with a negative 3 Tesla MRI.
2. Association between ROI (blurring cortical-subcortical junction/cortical thickening/transmantle sign/hyperintensity of grey and white matter/abnormal gyral-sulcal pattern/segmental or lobar hypoplasia) in the non- or semi-invasive workup modalities and in the ultra high field MRI data.
3. Histopathological diagnosis of surgical specimen.
4. Postoperative seizure outcome (Engel/ILAE class) minimally 1 year postoperative.
5. Intra-observer agreement between 2 ultra high field MRI scans (7T, 9.4T in 10 patients) that are performed in the same patient and assessed by the same observer. In addition, we will assess inter-observer agreement by repeating the assessment of the ultra high field MRI scans by a second observer.

Study description

Background summary

Rationale: 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.

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.
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, observational study

Study population: Patients with drug-resistant focal epilepsy undergoing pre-surgical work-up with a negative conventional 3T MRI but with a positive epileptogenic focus localization by means of other non- or semi-invasive modalities (MEG, PET, SPECT, EEG-fMRI, and/or seizure semiology and clinical history).

Intervention (if applicable): all (n =60) patient-participants will receive a 7T MRI-scan, without intravenous contrast administration. In 10 patients, two ultra high field MRI scans (7T and 9.4T), also without intravenous contrast, will be performed on two different days.

Main study parameters/endpoints:
Primary endpoint: the proportion of patients in whom apparent structural brain lesions are detected on ultra high field MRI.
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. Postoperative seizure outcome (Engel/ILAE class)
5. Differences in ultra high field MRI performed in the same patient

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
Burden: One visit to the ultra high field-MRI-unit of Scannexus, Maastricht (two visits for 10 patients).
60 Minutes of MRI-acquisition.
There are no specific risks associated with the used MRI protocols.
There are possible personal patient benefits in this study. 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.

Study objective

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 design

2 years data collection and 1 year follow up in all operated patients (max. 3 years) + 1 year analysis and publication

Intervention

All patients will undergo an ultra high field MRI-scan of the brain (in 10 patients twice, i.e. both 7T+9.4T).

Contacts

Public

Scientific

Eligibility criteria

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 (age 16 and above).
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
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2018
Enrollment:	60
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 54565
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7320
NTR-old	NTR7536
CCMO	NL66929.068.18
OMON	NL-OMON54565

Study results

Summary results

Colon AJ, van Osch MJP, Buijs M, van de Grond J, Boon P, van Buchem MA, Hofman PAM. Detection superiority of 7T MRI protocol in patients with epilepsy and suspected focal cortical dysplasia. Acta Neurol Belg 2016; 116(3):259-269