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.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20236

Bron
Nationaal Trial Register

Verkorte titel
EpiUltraTesla

Aandoening

Epilepsy Focal drug-resistant epilepsy

Ondersteuning

Primaire sponsor: Academic hospital Maastricht (azM), Maastricht, The Netherlands
Overige ondersteuning: No funding is received for this study.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The presence or absence of apparent structural abnormalities on Ultra high field MR brain imaging in patients with focal drug-resistant epilepsy.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Wetenschappelijk

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-12-2018
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 54565
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
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