Additional value of 7T MRI in patients with localisation related epilepsy and either a known focal cortical dysplasia or a MEG-focus but without abnormalities on 3 T MRI

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Pilot study on additional value of 7T as compared to 3T MRI

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

Summary

ID

NL-OMON36234

Source
ToetsingOnline

Brief title
7 to 3

Condition

- Seizures (incl subtypes)

Synonym
Epilepsy, Seizures

Research involving
Human

Sponsors and support

Primary sponsor: Epilepsiecentrum Kempenhaeghe

Source(s) of monetary or material Support: reserves eigen afdeling "onderzoek en ontwikkeling".

Intervention

Keyword: diagnosis, high field MRI, localisation related epilepsy, MEG

Outcome measures

Primary outcome

visualy detectable abnormalities

Secondary outcome

Abnormality type and characteristics

Raise or not of found abnormalities after adding localizing information

provided by MEG

Study description

Background summary

With the use of stronger magnetic fields in MRI (from 0.5 to 3 T) the percentage of patients with localisation related epilepsy in whom an underlying abnormality can be detected (noteably a focal cortical dysplasia) has grown (Von Oertzen). In addition, there are other functional investigational methods available, like MEG, that can give a clue on the localization of an epileptogenic focus (e.g. Ossenblok). At present MRI-machines with a field strength of 7T beconme available for human investigations. It is still unclear if this higher field strength can have an additional value in the diagnosis of localisation related epilepsy or if the gain of detailed information and a possible rise in artefacts will make diagnosis even more troublesome.

Study objective

Pilot study on additional value of 7T as compared to 3T MRI

Study design

Description of characteristics of known FCD when using 7T MRI
Blinded comparison of visual examination by neuroradiologist with specific

epilepsy experience and main investigator between MRI images of 3T vs 7T after state-of the art acquisition.
Re-examination of both after adding MEG-acquired knowledge.

Study burden and risks

Burden: Time of travel and time spend inside of the MRI. Depending on location of habitat of subject varying between 2 to 5 hours. Further more, subjects are requested not to move several minutes for several times while being inside of the scanner. This is standard procedure during MRI. As al subject already had an MRI they know what to expect.

Risks: We will apply only sequences that are approved for use in humans. As far as known there are no additional risks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

localisation related epilepsy
3T MRI with FCD
OR
3T MRI negative and Plausible MEG focus
Age over 17
able to give consent

Exclusion criteria

contra-indications for MRI

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-01-2012
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	12-12-2011
Application type:	First submission

Review commission: METC Leids Universitair Medisch Centrum (Leiden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL31157.058.11