Diagnostic criteria for Multiple Sclerosis: Impact of high field Magnetic Resonance Imaging

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To investigate the impact of high field 3T MRI on the diagnostic criteria in MS in a large multicenter study population using multiple vendor MRI systems.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	Observational invasive

Summary

ID

NL-OMON40083

Source
ToetsingOnline

Brief title
3T-CIS Trial

Condition

- Autoimmune disorders
- Demyelinating disorders

Synonym
MS, multiple sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Stichting MS Research (centrumsubsidie)

Intervention

Keyword: Diagnosis, Magnetic Resonance Imaging, Multiple Sclerosis, Neuroimaging

Outcome measures

Primary outcome

Primary endpoint of the study is MS lesion count: MR images from standard field 1.5T and high field 3T will be compared using total amount of lesions and region specific amount of lesions.

Secondary outcome

Secondary endpoints of the study: Data on cortical lesions: a double-inversion recovery (DIR) sequence is also included in the scanning protocol. This gray matter specific sequence leads to higher detection of cortical lesions. There is limited data on the quality of DIR at the various field strengths and vendors.

Study description

Background summary

High field 3 Tesla (T) Multiple Resonance (MR) imaging might influence the diagnosis of Multiple Sclerosis (MS), since it improves image resolution and signal-to-noise ratio and hence, MS lesion detection. The only study that followed a cohort of patients with a Clinically Isolated Syndrome (CIS) suggestive of MS scanned at 1.5T and 3T, showed that 3T imaging has a substantial influence on the classification according to MRI (Barkhof) criteria but does not lead to an earlier diagnosis of MS. However, it is too premature to take a definitive stand on the impact of higher field strength on diagnostic MRI criteria by using data from this one, rather small (40 patients), single-center and single-vendor cohort. The MAGNIMS (Magnetic Imaging in MS) group set up a large multicenter, multivendor study. The current protocol only applies to a part of this large MAGNIMS study, namely the patients that will be scanned in the VUmc, Amsterdam.

Study objective

To investigate the impact of high field 3T MRI on the diagnostic criteria in MS in a large multicenter study population using multiple vendor MRI systems.

Study design

Prospective study (being part of a larger multicenter study) comparing 1.5T MR and 3T MR imaging of CIS patients.

Study burden and risks

Time burden for participants will be (at 3 time points) a 1.5T MRI scan (max. 60 minutes), a 3T MRI scan (max. 60 minutes) and a clinical examination (60 min). However, the 1.5T MRI scan is made in a clinical setting, which means no extra burden for the CIS patients because this scan has to be made anyhow for determining further strategy for the patient. In total the time burden will be 360 minutes for patients (3T scan, clinical examination at 3 timepoints) and 360 minutes for healthy control subjects (1.5T and 3T MR scan at 3 timepoints). Risks of MRI at any field strength are low when standard procedures are followed. No intervention takes place, so no serious side effects are expected. There is a small chance that a subject will develop an allergic reaction to the use of contrast agent. To minimise this chance, subjects are excluded from the study if they had any allergic reactions to contrast enhancement in the past. Furthermore, they will be observed closely by a specialised team during the contrast administration and for some time after this.

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

CIS suggestive of MS as defined by the International Panel
Age 18-59 years

Exclusion criteria

Vascular, malignant or other immunological diseases at present or in the past medical history;MRI related exclusion criteria:
- Claustrophobia
- Foreign non MR compatible metal objects in the body
- Foreign metal objects in or close to the head
- Allergic reaction to contrast administration in the past (only for patients)

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-07-2013
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	01-05-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-04-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL42131.029.12