Feasibility study for a novel and clinically useful MRI sequence for imaging myelin in MS patients

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Ethical review	Approved WMO
Status	Completed
Health condition type	Demyelinating disorders
Study type	Observational non invasive

Summary

ID

NL-OMON41522

Source
ToetsingOnline

Brief title
Imaging myelin in MS patients

Condition

- Demyelinating disorders

Synonym
loss coordination, multiple sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Stiching MS research

Intervention

Keyword: MRI, multiple sclerosis, myelin water, T2 relaxation

Outcome measures

Primary outcome

Highly skilled radiologist from the VUmc will visually compare the standard diagnostic scans (a T2 weighted fast spin echo and a 3D T1 weighted scan) against the myelin water fraction images. All three types of scans will be compared to determine any additional information the myelin water fraction images may give. The healthy controls will provide a standard to judge the impact of MS on the myelin water fraction images of the patients. Any differences between lesions on the standard diagnostics images and the myelin water images will be tabulated.

Secondary outcome

N/A

Study description

Background summary

As myelin plays a center role in MS pathology, direct and reliable information on the state of the myelin in vivo would likely be valuable in diagnosis, prognosis and treatment monitoring. Previously, myelin itself has been largely invisible to MRI scans that were clinically practical. However, much of the in vivo pathology we do see on MRI scans appears to be secondary to demyelination. Being able to image myelin directly would allow the sub classification of MS lesion based on the amount of demyelination. There have been many reports in the literature of directly imaging myelin via myelin water, but those techniques have been too time consuming. Thus, being able to image myelin over the whole brain with useful resolution in a clinically acceptable scan time should be a very valuable tool for monitoring in vivo pathology in MS.

Study objective

In 2009, a new combination of MRI sequences was published by Deoni et al. (2009) that promised the ability to measure the myelin water in vivo over the whole head in a clinically useful time. Referred to as mcDespot (multi-component driven equilibrium single pulse observation of T1/2), the goal of this pilot project is to provide an initial assessment of potential usefulness of mcDespot in MS diagnosis, prognosis and treatment monitoring. This pilot project*s protocol, in addition to mcDespot, will include a conventional MRI diagnostic protocol for MS patients. mcDespot*s myelin images will be compared against the images of the diagnosis protocol by VUmc*s radiologists to see if mcDespot allows the sub classification of lesions based on the state of the myelin.

Study design

The study will consist of scanning subjects for less than 1 hour each with a set of MRI sequences. There will be 20 RRMS patients, 20 SPMS patients and 20 healthy controls in the cohort. The patients with a variety of in vivo MS pathologies, based on previous MRI scans, will be included into the cohort. In addition to the mcDespot sequences, the pilot studies protocol will include a conventional MRI diagnostic protocol for MS patients.

Whether mcDespot provides new and potentially useful information for sub classifying MS lesions will be assessed by comparing the images from the standard MRI sequences against the mcDespot*s myelin images by highly experienced radiologists at the VUmc.

If the pilot project determines that mcDespot appears to provides useful new information on vivo MS pathology, additional studies will be conducted to determine how relevant new sub classification are. These studies would likely include nature history, diagnosis, prognosis and correlation with postmortem pathology.

Study burden and risks

Volunteers will be asked to come to the hospital only once and only for a single MRI scan. No contrast agent will be administered. Volunteers will be asked to lie still in the scanner for a maximum duration of 1 hour. To reduce the sound levels earplugs are provided. Volunteers can also choose for music during the examination. During the scans some small breaks are planned to ask for the volunteers well being and allow them to cough or relieve other discomforts. MR scans are considered to have negligible risks. Before the examination volunteers will be checked for metal objects in their body, risk of claustrophobia or other excluding criteria.

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

* Clinically definite MS (according to the subgroups)
* Age between 18 - 60 years of age (to exclude age related chance of other neurological disorders)
* EDSS < 5.5 (despite the fact that especially for SP patients this criterium lowers the number of available volunteers, the physical efforts necessary to complete the protocol may be hard for this group)

Exclusion criteria

* Clinically isolated syndrome
* Other neurological disorders

* Claustrophobia
* Foreign non MR compatible metal objects in the body
* Foreign metal objects in or close to the head

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	26-04-2011
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	02-12-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-05-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-09-2015
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	NL33748.029.10