Optimization of new MR protocols in clinical setting

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Facilitation of translation of MR protocols from research to clinical setting.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON45021

Source
ToetsingOnline

Brief title
Patient research MR (PTMR)

Condition

- Other condition

Synonym
Patients with a clinical indication for MR examination

Health condition

Alle aandoeningen waarvoor een klinische indicatie voor MR onderzoek

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Clinical patients, Magnetic Resonance Imaging, Protocol optimization

Outcome measures

Primary outcome

The results of the additional MR acquisition methods may be evaluated for image quality, may be compared with those of conventional MR techniques, and/or results in clinical patients may be compared with the results (previously) obtained in healthy volunteers. The additional MR acquisition methods could be assessed for their incremental value, aspects for further optimization could be identified and these could be incorporated in the continuing process of development. Final step in this translation project is potential publication of the results obtained by application of the additional MR protocols in clinical patients. During this project more and better MR techniques and analysis tools will become available for research purposes and patient care.
Main study parameters/endpoints will be described for each pilot study in an addendum.

- Addendum 01 15/12/2015: myocardial triglyceride accumulation, native T1 relaxation times, ECV quantification, fibrosis/fat ratio.
- Addendum 02 06/11/2017: LIF score, fat fraction, T1 times, T2 times.

Secondary outcome

Not applicable

Study description

Background summary

Magnetic Resonance Imaging (MR) is continuously developing with a wide spectrum of different (functional) contrasts, resulting in new applications each year. These techniques are developed for both ultrahigh fields (7 Tesla) and clinical field-strengths (1.5 and 3.0 Tesla), for advanced anatomical and functional imaging, and for research purposes and daily clinical routine. The process of development of these techniques includes phantom experiments and small pilot studies in healthy volunteers (n<20).
However, the requirements of new MR techniques may differ when applied to the healthy volunteer as compared to application in the clinical patient, for example due to differences in subject biometrics and differences in imaging conditions in research versus clinical setting. Also, selection of techniques to be evaluated in clinical studies in such a setting is difficult, when only normal volunteer data is available, Therefore, small pilot studies in the patient group of interest are necessary to come to final optimization, evaluation and validation of these MR protocols. Also, image processing and analysis techniques of MR data derived from new acquisition protocols can only be fully developed in case patient data is available, with pathology present and/or with a wider range of physiological contrast. This enables optimization of MR data analysis methods in its sensitivity and specificity for diagnosis of the state of disease of interest.

Study objective

Facilitation of translation of MR protocols from research to clinical setting.

Study design

Observational. Patient inclusion implies extension of the clinical MR examination by an additional MR protocol.
Details on study design will be specified for each pilot study in an addendum.

- Addendum 01 15/12/2015: 1H-MRS (proton magnetic resonance spectroscopy) and native T1 mapping and extracellular volume (ECV) quantification in patients diagnosed with/clinical suspicion of cardiomyopathy.
- Addendum 02 06/11/2017: non-Invasive rapid assessment of patients with liver transplants using Magnetic Resonance Imaging with LiverMultiScan

Study burden and risks

MR acquisitions will be added to the conventional clinical MR examination, with a maximum prolongation of 15 minutes. None of the additional MR acquisitions

will involve additional injection of contrast agents or medication. If applicable, invasive interventions such as overnight or morning fasting and /or collection of blood samples will be motivated in an addendum.

- Addendum 01 15/12/2015: 6 hours fasting; blood sampling for interpretation of MR data.
- Addendum 02 06/11/2017: 4 hourts fasting; no blood sampling.

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

Clinical indication for MR examination
Addendum 01 15/12/2015: diagnosis/clinical suspicion of cardiomyopathy
Addendum 02 06/11/2017: Patients over 18 years old with a liver transplant, due to undergo

routine liver biopsy or biopsy for suspected pathology after liver transplantation

Exclusion criteria

All contra-indications for MR examinations (claustrophobia, cardiac pacemaker, implants not approved for MR at the employed field-strength, metal objects, etc)
Incapable to undergo prolonged MR examination additonal to clinical MR examination (due to frailty of old age, general condition, ect).
No informed consent for notification of study participation to the medical specialist .
No informed consent for the work-up of incidental findings.;Addendum 01 15/12/2015: medical history of diabetes mellitus and/or medication use diabetes mellitus
Addendum 02 06/11/2017: any contraindication to liver biopsy (coagulopathy, obstructed biliary tract with high risk bileleak, ascites etc)

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):	02-06-2017
Enrollment:	1000
Type:	Actual

Ethics review

Approved WMO

Date:	07-01-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO Date:	13-07-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	13-11-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL52871.058.15