MRI protocol development at clinical field strengths

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To further optimize MRI techniques and to develop new MRI techniques that will enable state-of-the-art clinical and cognitive research and will lead to improved patient care on MR scanners of clinical field strengths (

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

Summary

ID

NL-OMON35342

Source
ToetsingOnline

Brief title
PROTO-MRI

Condition

- Other condition

Synonym
Healthy control subjects

Health condition

Gezonde vrijwilligers

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: Magnetic resonance imaging, MR-physics, Normal volunteers, Protocol development

Outcome measures

Primary outcome

Improvements of scan techniques and development of new techniques are the main

outcome of this study. These techniques will be employed in clinical research

and patient care.

Secondary outcome

Small pilot studies performed for evaluation and technical papers will be

published.

Study description

Background summary

In the last three decades MRI has revolutionized our understanding of the human body and how disease can affect it. Especially, for studies of the brain, joints, spinal cord, and the heart, MRI has opened new avenues for diagnosis of disease and has increased our basic understanding of anatomy, pathology, physiology and metabolism in humans. It has become one of the central modalities in every radiological clinic. MRI is a continuously developing modality, requiring continuous optimization and implementation of newly emerging techniques.
The rapid expansion of MRI applications over the last 30 years can be attributed mostly to improved hardware and acquisition techniques. Interestingly, this has increased the number of different contrasts that can be achieved with MRI. First, anatomical imaging was developed, followed by angiographic techniques and spectroscopic techniques that enable the measurement of concentration of metabolites. Around 1990, it was discovered

that MRI could enable the identification of the location of brain activation, which revolutionized cognitive research. Later, physiological techniques were proposed to measure tissue perfusion, blood volume, and oxygenation. In recent years, new techniques have been proposed, like pH measurement, myelin imaging, iron quantification, that are not yet accepted by the radiologically clinic, but are already employed in clinical research. To further optimize existing techniques, to bring recently proposed techniques towards clinical research and diagnostics, and to propose even newer ones, MR physics research will remain necessary. This will also further enhance the clinical research within the LUMC.
The MR physics research in the LUMC has increased considerably with the installation of the 7 Tesla MRI scanner in 2006. The investigational nature of this scanner made it mandatory to not only invest in new hardware, but also in MR physics researchers to further develop ultra-high field MRI. These researchers want to extend their activities also to lower, clinically used field strengths for three reasons:
1. Many clinical studies are running on these lower field strengths, because of their robustness, easier patient handling, less contra-indications, availability of scan time, and their national availability (i.e. multi-center studies). Therefore, it is essential that new or improved techniques do not only run on the 7Tesla scanner, but also on lower field strengths to enable their application in clinical studies
2. Worldwide 99% of the MR research is still performed on these lower field strengths. For the impact of the developed techniques it is therefore necessary to prove their performance on these field strengths
3. Whereas for some techniques 7Tesla is clearly showing huge improvements, for other applications it will require much more hardware and software developments before successful application will be feasible. For some of these techniques it is better to first optimize and develop methods at lower field strengths and only after this additional experiences (maybe) move to 7Tesla.

Study objective

To further optimize MRI techniques and to develop new MRI techniques that will enable state-of-the-art clinical and cognitive research and will lead to improved patient care on MR scanners of clinical field strengths (<4 Tesla). Typical applications that will be studied are anatomical imaging of the vessel wall, hemodynamic imaging, susceptibility weighted imaging, quantitative MRI techniques, MR spectroscopy, fMRI and DTI techniques.

Study design

Studies will be performed by qualified personnel (i.e. having a *scan brevet* as provided by the MR safety committee of the department of Radiology) and according to the standards of the Radiology department (participants will therefore in principle receive double ear protection (ear plugs and head phone), will be allowed to listen to music when possible, etc).

An MR session for this study will be approximately 1 hour. The volunteer will be informed prior to the MRI examination of the anticipated duration and can of course always stop the study without any explanation. For some studies it will be necessary to record respiratory and/or cardiac signals to minimize artifacts in the MRI images arising from the moving heart and lungs. These physiological signs are recorded with equipment provided by the scanner manufacturer (Philips Healthcare) and are an integral part of the MRI scanner. Furthermore, it might be necessary for the volunteer to perform a small task (looking at a flickering checkerboard, fingertapping, etc) to evoke neuronal activation. During the session, the volunteer will always be in direct contact with the MRI operator by means of an alarm bell (the volunteer will be in full control) and an intercom system. The operator will inform the subject about the progress of the session and will check on the volunteer*s well-being. Whenever the subject feels uncomfortable, the session will be ended immediately. At the end of the session a verbal post-imaging interview will be held to identify discomfort of the study. If the subject indicates significant discomfort, the radiologist on duty is informed and a side-effects form is completed. This form is sent to the MR safety committee of the Department of Radiology and if the discomfort is considered to be serious they forward the form to the CME.
It should be noted that MRI at clinical field strengths is considered to be absolutely safe when operated correctly and that it is already employed in the LUMC for more than 25 years without any serious damage to patients, workers or volunteering subjects.
Studies will be designed like normal MR physics research. This includes:
1. Defining a research goal
Based on their own experiences, experiences of radiologists, clinical researchers, or cognitive researches, a certain artifact of a current protocol or a development request for a new MRI technique will be identified and an approach to solve this research question will be developed.
2. Improvements in acquisition-parameters or pulse sequence
Elimination of artifacts and development of new applications in MRI can most often be resolved by means of tuning of acquisition parameters. Based on the hypotheses of the origin of the artifacts or the required information, optimization of acquisition parameters is performed in vivo by systematically changing the MR parameters involved (an MRI scanner has more than 100 parameters accessible even to a normal technician, on the next level accessible only to MR physicists this number increases by approximately a factor of 10). Such optimization procedures should be performed in several subjects to obtain robust settings that are subject independent.
Whenever tuning of acquisition parameters does not yield the necessary results, redesign of the pulse sequence should be performed. This may involve compiling a new software version of the scanner. New pulse sequences are always first tested in phantoms, before being tested and optimized in vivo. After each step in the optimization process, a quality survey will be performed, for example in collaboration with a radiologist.
3. Evaluation study
Finally, a newly developed sequence should be subject of a small pilot study

and compared to the starting sequence, to a physiological test (e.g. detection of brain activity) or literature values. This will show whether the quality is sufficient for clinical research and/or patient care and may form the basis for an article in a scientific journal. Pilot studies will be limited to a maximum of 20 subjects.

Study burden and risks

MRI is a completely safe modality. Subjects will be in the scanner for approximately 1 hour.

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

Healthy male and femal subjects older than 18 years and younger than 65 years

Exclusion criteria

All contra-indications for MRI (metal implants, claustrophobia, pacemaker, etc
Mentally disabled persons
Under treatment of a medical specialist or under treatment of a medical specialist in the last year
A chance of being pregnant (as reported by the volunteer)
Not having a general practitioner
Younger than 18 years
Older than 65 years

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-07-2011
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO

Date:	05-10-2011
Application type:	First submission

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	NL37703.058.11