7 Tesla MRI protocol development

Published: 13-08-2007
Last updated: 10-08-2024

To further optimize 7.0 Tesla MRI techniques and to develop new MRI techniques that will enable state-of-the-art clinical and cognitive research leading to improved patient care. Whereas some applications of 7.0 Tesla MRI already show improvements...

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

Summary

ID

NL-OMON43914

Source
ToetsingOnline

Brief title
7T MRI

Condition

- Other condition
- Inner ear and VIIIth cranial nerve disorders
- Eye disorders NEC

Synonym
control subjects/normal subjects

Health condition

gezonde proefpersonen

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: NWO-BIG;STW,diverse subsidies o.a. reumafonds;CTMM;etc

Intervention

Keyword: High field MRI, Magnetic Resonance Imaging, Magnetic Resonance Spectroscopy

Outcome measures

Primary outcome

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

outcome of this study. These scans will be utilized in clinical research and

patient care.

Secondary outcome

Small pilot studies performed for evaluation of image quality will be

published.

Study description

Background summary

The quality of magnetic resonance imaging (MRI) has been improved considerably since it was first applied in the medical arena. A major contributor to this development is the surge for an increase in magnetic field strength: two years ago 1.5 Tesla was still the clinical standard, now 3.0 Tesla has shown much higher quality especially for neuro-imaging. A stronger magnetic field leads to higher quality images and enables new kind of measurements not feasible at low or medium field strength MRI scanners. At the moment a 7.0 Tesla MRI scanner is being installed at the LUMC. This brings the LUMC the potential to take the quality of MR images to the next level. However, the technology of the 7.0 Tesla is not fully developed yet and therefore the 7.0 Tesla scanner should be regarded as a research scanner. Most scan techniques need further development before they can successfully be employed in clinical research or patient care.
It is essential to be able to scan normal volunteers to enable this optimization. Techniques that will be optimized are:

- Anatomical imaging (T1,T2, PG, angiography, high resolution imaging, etc)
- Functional imaging (brain activation, perfusion, diffusion)
- Metabolic status (MR spectroscopy)
Whereas the main focus will be brain imaging, it is also anticipated that research will be performed on the knee, ankle, heart, and carotid arteries.

Study objective

To further optimize 7.0 Tesla MRI techniques and to develop new MRI techniques that will enable state-of-the-art clinical and cognitive research leading to improved patient care. Whereas some applications of 7.0 Tesla MRI already show improvements compared to clinical scanners, the potential of ultra-high field MRI is much higher. Typical applications that will be studied are: ultra high resolution anatomical imaging (MR microscopy), hemodynamic imaging, susceptibility weighted imaging, quantitative MRI techniques, MR spectroscopy, fMRI and DTI techniques. Since the underlying technical problems are comparable for all these techniques, the development of these techniques will be performed parallel to each other. From the technical viewpoint, the goals of this study will be to develop imaging pulses insensitive to RF and magnetic field inhomogeneities, optimization of imaging parameters, design of optimal shimming techniques, study interactions between tissue and RF, limit artifacts from physiological processes, and to develop more homogeneous RF distribution.

Study design

Studies will be designed like normal MR physics research. Several stages can be identified:
1. Characterization
Measuring basic tissue properties that determine MRI contrast, like T1, T2* and proton density for the region of interest. Secondly, this stage employs state-of-the-art imaging as based on literature to identify current quality.
2. Assessment of quality and identification of potential technical problems
Image quality is assessed during consensus meetings by radiologists and MR physicists and if image quality is deemed insufficient, hypotheses are generated about the origin of the artifacts or limited signal-to-noise ratio.
3. Improvements in acquisition-parameters or pulse sequence
Most artifacts in MRI can be resolved by means of tuning of acquisition parameters. Based on the hypotheses of the origin of the artifacts, optimization of acquisition parameters is performed in vivo by systematically changing the MR parameters involved. 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 enough improvement, redesign of the pulse sequence should be performed.
After each step in the optimization process, one should go back to step 2 and conduct a quality survey with a radiologist.
4. Evaluation study

Finally, a newly developed sequence should be subject of a small pilot study and compared to the starting sequence, to a comparable sequence at 3.0 Tesla, to a physiological test (e.g. detection of brain activity) or literature values.

Study burden and risks

In 1997 an 8 Tesla MRI scanner was installed in Ohio State University. Early research focussed on the safety of ultra-high field MRI. They especially focussed on cardiovascular effects (first in pigs, later on humans) and on more subjective signs of comfort. Literature shows furthermore studies on cell reproduction, cell function, thrombolysis, nerve function, cardiovascular effects, body temperature change, magnetophosphenes, and cell alignment. None of these studies show conclusive evidence for irreversible, hazardous side effects to acute, short-term and long term exposure to a static magnetic field (see a recent publication by the World Health Organization, ISBN 92 4 157232 9). We refer to the project proposal for a more detailed description of the safety aspects of ultra-high field MRI. Post-exam interviews of the first 100 volunteers showed that approximately 30-40% volunteers experienced some dizziness when positioned inside the scanner. These effects last only shortly.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Male and female subjects older than 18 years

Exclusion criteria

All contra-indications for MRI (metal implants, claustrophobia, pacemaker, etc)
Pregnancy
Mentally disabled
Not having a general practitioner
For heatlhy control subjects: receiving medical treatment at the moment or in the year preceding the study.

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):	13-08-2007
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO Date:	02-05-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	30-05-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	27-08-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	07-11-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	12-05-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	17-10-2016
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	NL16198.058.07