Protocol development for a Very Low Field (0.047 T) MRI system

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

Summary

ID

NL-OMON53693

Source
ToetsingOnline

Brief title
Very low field MRI protocol development

Condition

- Other condition

Synonym
N.A.

Health condition

MR protocol development

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum
Source(s) of monetary or material Support: NWO Domain - Applied and engineering sciences (AES);European Research Council (ERC);National Institute of Health (NIH)

Intervention

Keyword: Brain, Extremities, MRI, Very Low field

Outcome measures

Primary outcome

The first study parameters of this project are quantitative measurements of MR image quality with respect to the commercial Hyperfine system which operates at a similar field strength. Specifically, we will compare T1, T2, T1*, T2*, magnetisation transfer and diffusion images in the brain, since these are the quantities that are in the approved Hyperfine protocol. From this data, we will perform quantitative analysis (signal-to-noise ratio (SNR), contrast-to-noise ratio (CNR)).

In addition, we will develop sequences to look at fat/water imaging in the human calf muscle/forearm (these cannot be performed on the Hyperfine system since the closed geometry of the RF coil only allows brain imaging).

The second aim is to investigate a number of different types of image processing on the image quality, since with our self-developed system we have complete access to the raw data being acquired. We will quantitate improvements in image quality in terms of SNR measurements, as well as scoring from our (neuro)radiologists.

Secondary outcome

None

Study description

Background summary

Very low-field (VLF, <0.1 T) portable MRI scanners are emerging as a new category of systems with much lower costs than conventional MRI scanners and the ability to be used in sites and applications where conventional MRI is impossible.

In September 2022 we received approval from the METC to start scanning human volunteers on a commercial VLF MRI system from Hyperfine, specifically for protocol optimization for a number of different contrasts. This study has started and is providing very useful information on how best to set up such protocols. However, the Hyperfine unit is an expensive commercial system, with limitations on open software development as well as hardware adaptations, which places it outside the realm of many low and middle income countries (LMICs), for example. We have extensive funding from the National Institutes of Health, the European Research Council and the NWO to develop a VLF system with increased portability, lower cost and open-source hardware and software which can be used in LMICs.

In this proposal we intend to study a number of different aspects of VLF MRI. These studies will be performed in parallel to those on the Hyperfine unit, allowing comparison of results and optimization of many aspects of the LUMC VLF unit. In addition to a study to optimize image contrast in the brain using a number of different MRI techniques, which will parallel the approved study on the Hyperfine, we will evaluate a number of techniques for enhancing image quality which cannot be performed on a commercial system, namely:

i) Active noise cancellation
ii) Correction for small drifts in the magnetic field during the scan
iii) Undersampled data collection and AI reconstructions

In addition to neurological measurements, the flexibility of our 0.047 T system allows other parts of the body to be studied, unlike the Hyperfine system. We will develop techniques to measure the lipid/muscle content in both the arm and leg, which can ultimately be used in the estimation of malnutrition in developing countries.

Dissemination of findings will be performed via articles in world leading journals on MR techniques. Such developments and publication of results are common to the MR community, and lead to a continuous development and improvement of the capabilities of MR scanners.

Study objective

Our overall aim is to measure several distinct MR parameters at 0.047 Tesla, and to use these to derive optimal MRI-protocols in terms of contrast and SNR. The images produced will then be compared with those from the commercial Hyperfine system. Some of these new developments may subsequently be used in clinical research protocols (which are not a part of this protocol), other developments are more fundamental technical MR developments for which applications will only benefit in the future.

Study design

Only projects aiming at the development, optimization and/or interpretation of non-invasive MR techniques are included. MRI-protocol development will follow the usual roadmap of MR physics research that consists of an iterative process of identification of new requirements or artefacts in existing techniques, MRI-protocol optimization, sequence development, pilot experiments, quality review meetings, and finally back to identification of sources of artefacts. For each of the studies (noise cancellation, data undersampling, SNR comparisons for six different MR contrast mechanisms, and development of lipid/muscle ratios we will scan 20 healthy volunteers (total number=240) to publish results of these new protocols/sequences.

Study burden and risks

All of the issues concerning safety and risk at 0.047 T are much lower than the corresponding considerations at clinical MRI field strengths (1.5 and 3T). Projectile forces are proportional to the magnetic field multiplied by the spatial gradient of the magnetic field, as so are ~30 and 60 times less than 1.5T and 3T respectively, power deposition in the subject is proportional to the square of the magnetic field, so is ~900 and 3600 times less than at 1.5T and 3T. The scans are almost silent, no special clothing is needed, and the environment is much less claustrophobic than for a conventional MRI scan. Many thousands of scans have been performed on both patients and healthy volunteers on VLF scanners with field strengths of 0.08 and 0.064 T.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Healthy volunteers between the age >18 years or <65 years

Exclusion criteria

- Age <18 years or >65 years
- Persons with reduced mental capacity
- Pregnancy and a chance of being pregnant (as reported by the volunteer)
- Not having a general practitioner
- MRI contraindication e.g. cardiac pacemaker, implants not approved for MRI (see www.mrisafety.com), claustrophobia, tinnitus.Decision on the MRI contraindication is made according to the guidelines outlined in the MR safety document of the Department of Radiology which can be found in the attachment (*MRI Veiligheidsrichtlijnen LUMC (BPPC-protocol)*).

Study design

Design

Study type: Observational non invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-06-2024
Enrollment:	276
Type:	Actual

Medical products/devices used

Generic name:	OSII One
Registration:	No

Ethics review

Approved WMO

Date:	12-05-2023
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	05-02-2025
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	NL83272.058.22