Protocol development for a Hyperfine Very Low Field (0.064 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-OMON51553

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: Radiologie
Source(s) of monetary or material Support: NWO Domain - Applied and Engineering Sciences (AES)

Intervention

Keyword: Brain, MRI, very low field

Outcome measures

Primary outcome

The main study parameters of this project are quantitative measurements of MR parameters. Specifically, we will measure T1, T2, T1*, T2*, magnetisation transfer and diffusion in the human brain. From this data, we will perform quantitative analysis (signal-to-noise ratio (SNR), contrast-to-noise ratio (CNR)). Having measured these, we will design optimized imaging protocols which will be quantitatively compared with those currently available on the system

Secondary outcome

None

Study description

Background summary

Very low-field (<0.1 T) portable MRI scanners are emerging as a new category of systems with much lower costs than conventional systems and the ability to be used in sites and applications where conventional MRI is impossible. In spring 2022 the LUMC Department of Radiology, in collaboration with the Gates Foundation, obtained a Hyperfine Swoop 0.064 T portable MRI scanner. The purpose of our collaboration is to perform MRI-protocol development to optimize image contrast in the brain using a number of different MRI techniques. Since MR parameters are much less studied at very low field than at conventional clinical field strengths, this will involve measuring each MR parameter in a number of healthy volunteers to derive optimized parameters and show that image

contrast is improved compared to existing techniques on the system. 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 0.064 Tesla, and to use these to derive optimal MRI-protocols in terms of contrast and SNR. 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

We note that there will be no data collection for medical research. 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 6 different MR contrast mechanisms, we will scan 20 healthy volunteers (total number=120) to evaluate the consequent optimisation of Signal-to-Noise Ratio (SNR) and Contrast-to-Noise Ratio (CNR) and to publish results of these new protocols/sequences.

Study burden and risks

All of the issues concerning safety and risk at 0.064 T are hundreds/thousands of times lower than the corresponding considerations at clinical MRI field strengths (1.5 and 3T), further details can be found in the risk and analysis sections of the attached IMDD. Although the Hyperfine Swoop currently does not have a CE mark, it was FDA approved in 2020 and so has been extensively tested with respect to safety and risk/benefit.
26-07-2022

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, metal objects attached to the body that cannot be removed

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):	01-03-2023
Enrollment:	120
Type:	Actual

Medical products/devices used

Generic name:	Hyperfine Swoop
Registration:	No

Ethics review

Approved WMO

Date:	02-09-2022
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	NL81853.058.22