Feasibility study Mid-Field (0.6 T) MRI system

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

Summary

ID

NL-OMON57445

Source
ToetsingOnline

Brief title
Mid-Field MRI

Condition

- Other condition
- Cardiac disorders, signs and symptoms NEC
- Headaches

Synonym
Not applicable

Health condition

Daarnaast abdomen, knie, long, wervelkolom

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Health~Holland

Intervention

Keyword: 0.6T, Brain, Cardiac, MRI

Outcome measures

Primary outcome

We will assess the quality of mid-field MRI in the previously mentioned anatomical regions compared to the routine diagnostic approaches as requested for the patient. This qualitative assessment allows to identify both diagnostical questions that are very feasible to answer as questions that need further technical refinement or will remain high-field MRI in the future.

The second endpoint is to provide novel MRI methods specific to mid-field MR to increase the obtained information in limited scan time, to improve patient comfort and to reduce costs related to acquisition and operation of an MRI scanner.

Secondary outcome

N.A.

Study description

Background summary

Currently, access to MRI is limited due to costs (purchase, siting and maintenance), the need for skilled personnel that is scarce, and safety issues that require a hospital setting. The complexity and costs of MR scanners as well as the safety issues are almost directly related to the magnetic field strength. Mid-field (field strength between 0.1 T and 1 T) MRI scanners have

found renewed attention of industry and academia in the last years to reduce costs and improve accessibility to MR. The improved hardware around the main magnetic field and AI-powered reconstruction techniques provide ways to mitigate the reduced signal from the lower main magnetic field. Mid-field scanners have the potential to be placed in different environments such as a community centre, closer to the GP, moving MR closer to the first line in health care. Moreover, the lower magnetic field strength allows to make the scanner more patient friendly, due to the possibility to widen the bore, more silent imaging and fewer safety procedures.

A prototype 0.6 T MR scanner has been developed by Philips, based on a commercially available 1.5 T MR scanner. A scanner of this type will be placed in a side building of the LUMC by late 2024. Researchers of the LUMC already gained experience and optimized standard sequences in healthy volunteers in the past year at the same system as installed at the Philips plant in Best.

Through this study we further want to study what the potential role of a 0.6T MR scanner could be in the Dutch healthcare system to increase the diagnostic capacity of the first line of defence (GP practices) and to help triaging patients for hospital referral. The prerequisite for assessing this role of mid-field MRI is clinical research to study the clinical value of the obtained images in comparison to imaging or non-imaging diagnostic methods that currently are standard care, and technical research to optimize scan protocols and new scan methods for mid-field partly based on the lessons from patient scans. Technical research will include improved image quality and reduced scan-time, multi-parametric mapping, fat suppression techniques, reduced acoustic noise levels and lowered hardware requirements. In the translational, clinical research we aim to study applications for brain, cardiac, lumbar spine, knee, abdomen, (prosthetic) joints, whole body and lung.

Dissemination of technological findings will be performed via articles in world leading journals on MR and radiology and the impact on the healthcare system will be disseminated in medical journals. The technological developments we pursue in this project are important to both the MR as well as the medical community, since they open up avenues for new utilization of MRI in the healthcare system.

Study objective

Our overall aim is to develop mid-field MRI systems for low-threshold, extramural service to GP practices that can contribute to making healthcare more sustainable. In this study we want to perform the first steps towards this general aim. On one hand, we aim to improve image quality and develop several new techniques that improve patient comfort, reduce placing costs and/or easy operability. Some of these techniques can directly be productized, other insights will be used in future MR research and development. On the other hand and in parallel, we aim to explore what types of pathology that GPs often

need additional diagnostic tests can reliably be detected with mid-field MR. This will potentially lead to further, more specific clinical research studies.

Study design

In this study brain, cardiac, lumbar spine, (prosthetic) joint, knee, abdomen, whole body and lung imaging will be performed. To get a broad sample of potential applications, no specific diagnostic questions are filtered. Therefore, we will include patients where one could expect mid-field MRI to provide sufficient image quality, but also include patients in which poor performance is expected to allow a realistic estimation the diagnostic value over a wide range of application. After the scan we will perform a survey with the patients to incorporate feedback on comfort and scan experience. The diagnosis based on the acquired images will be compared to the standard diagnostic approach to perform a qualitative feasibility assessment. For each anatomical region 50 patients (making the total 400) will be scanned to incorporate a wide range of pathology for each organ to get a proper impression of the performance of the new MRI scanner.
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 (image quality improvement/reduced scan time per anatomical region, multi-parametric mapping, fat suppression, acoustic noise reduction, lowered hardware requirements, total 12) a maximum of 40 healthy volunteers will be scanned (maximum total number 480).

Study burden and risks

The used scanner is based on a commercially available model (1.5T), brought down to a lower field strength of 0.6T, reducing projectile forces with a factor 2.5 and power deposition with a factor 6.25[1]. All normal safety checks will be performed as for 1.5T, minimizing risks. Extensive tests and scans, both on phantoms and in vivo have been performed by Philips. LUMC-employees have participated in extensive scanning at the 0.6 T scanner in the Philips factory, including scans of human volunteers and elderly subjects. The questionnaire will take a short time.

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

1. Patients: older than 18 years;
Healthy control subjects: age between 18 and 65 years old.
2. Patients: Medical diagnostics requested focused at brain, back, knee, lung, cardiac, (prosthetic joints), whole body MRI or abdomen.

Exclusion criteria

3. Age <18 years or (only for healthy control subjects) older than 65 years old
4. Persons with reduced mental capacity that would make informed consent impossible
5. Pregnancy and a chance of being pregnant (as reported by the volunteer or patient)
6. Not having a general practitioner
7. MRI contraindications (see www.mrisafety.com) or claustrophobia. 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)*). Subjects

suffering from tinnitus will be warned for the (potential) loud noise of the scanner and will confirm that they considered the noise level into account when providing informed consent.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-04-2025
Enrollment:	880
Type:	Anticipated

Medical products/devices used

Generic name:	Ambition MRI system
Registration:	No

Ethics review

Approved WMO

Date:	25-04-2025
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	NL87916.058.24