# Development of MRI technology for improved visualization and quantification of tissue and organs in healthy volunteers

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1) Optimize new or modified MRI sequences/technology for the visualization and quantification of tissue structure and physiological processes. 2) Test the optimized MRI sequences/technology against commercially-available, clinical MRI sequences in...

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

## Summary

### ID

NL-OMON47106

**Source**
ToetsingOnline

**Brief title**
Development of MRI technology

### Condition

- Other condition

**Synonym**
tissues and organs

**Health condition**

gezond

**Research involving**

Human

## Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Development, healthy volunteers, MRI-technology, Sequences

## Outcome measures

### Primary outcome

Generally, data will be collected and analysis techniques will be used as appropriate for the specific project and its purpose. The following parameters are likely to be collected:

* Overall Image quality and (physiological) artifacts will be ranked on a five point scale.

* SNR and CNR (lesion versus background) will be measured.

* Calculation of quantitative parameter values (e.g. T1, T2) when relevant.

### Secondary outcome

* If applicable, the reproducibility of derived quantitative parameters will be asessed, and these parameters will be compared with reference values from literature (if available) or with reference values derived from standard clinical MR series.

* If applicable, the results of (semi-)automated image post-processing techniques will be compared with manual annotations in terms of accuracy, reproducibility, and robustness.

* If applicable, the presence of false positives or false negatives (using the

standard clinical MR series as ground truth) will be assessed.

* If applicable, workflow aspects will be documented and analyzed.

# Study description

**Background summary**

Magnetic Resonance Imaging (MRI) is a technique which allows the visualization of the human body with a strong magnetic field. After positioning of a volunteer or patient in the MRI scanner radio frequent waves are submitted and absorbed by the body. These RF waves are released and detected by coils in the MRI scanner. This technique is non-invasive, without radiation exposure, without side-effects and it can easily be repeated.
Normally, multiple scans are performed during one MRI examination. Each MRI scan, which is called MRI sequence has its own parameter setting. Each sequence has its own characteristics and image contrast. For example, in one sequence, fluid is depicted as a dark structure, while in another sequence fluid is depicted as a white structure. The length of the sequence is the main determinant of the signal to noise in the image. An increased signal to noise can be used to improve the resolution of the image. The more sequences are performed during one MRI exam, the more information is gathered. For optimal MRI exams, the patient has to cooperate by lying quiet in the scanner without motion.
Most patients or healthy volunteers can only undergo an MRI exam for a restricted amount of time for logistical reasons due to the need for an efficient use of the scanner time, claustrophobia and/or the restricted duration that a patient or volunteer can be quiet without motion. Most patients cannot exceed the 45 minutes, while volunteers can undergo a MRI scan for more than 90 minutes.
For these reasons, each MRI exam is a compromise between number of sequences, scan time, image resolution and signal to noise ratio.

MRI technology (scanner, sequences en analysis software) is improved constantly due to an increase in scientific knowledge, technical improvements and the needs of the clinical and scientific users. After the first steps in the development of new technology, it enters a phase of optimization, testing and evaluation in a clinical and scientific environment to assess the real potential of the technology, before large scale application of a commercial product can be promoted.
Optimization, testing and evaluation of new or modified sequences/technology is first performed on phantoms. Thereafter, optimization, testing and evaluation has to be performed in healthy volunteers. The MRI sequences/technologies are not yet approved for diagnostic use, but the MRI company has received a CE mark

for investigational use only (Appendix 1).
The MRI sequences involved are developed for imaging of all body organs, including but not limited to head, neck, chest, heart, abdomen, extremities.

At that moment the relevant questions are:
* What is the optimal parameter setting of a specific new or modified MRI sequence. In other words, Which parameter setting provides the best image quality/ information. verkregen. Parameter setting of a sequence is optimal as it provides the available information in a restricted scan time with high resolution?
* Is the sequences performing properly in humans. In other words, are images which good quality obtained in healthy volunteers?
* How good performs the MRI sequence/technology in comparison to existing sequences?
* Are new applications foreseen with the new or modified MRI sequences/technology. In other words can structures be detected or physiological parameters be measured which could not be detected or measured with previously developed sequences/technologies.

Optimization, testing and evaluation of MRI sequences/technologies in humans is first performed in healthy volunteers as they are able to undergo a lenghty MRI exam. Some sequences are optimized for the depiction of vessels, perfusion of organs or the enhancement after contrast injection. Therefore optimization, testing and evaluation of some MRI sequences/technologies requires the injection of contrast agents.
The proposed studies will demonstrate what the additional value is of new or modified MRI sequences/technology in the visualization and/or quantification of tissues and organs. The studies will make clear whether the next phase, evaluation in patients, is warranted.

**Study objective**

1) Optimize new or modified MRI sequences/technology for the visualization and quantification of tissue structure and physiological processes.
2) Test the optimized MRI sequences/technology against commercially-available, clinical MRI sequences in terms of image quality, signal-to-noise ratio (SNR), contrast-to-noise ratio (CNR), speed, and accuracy/reproducibility of extracted quantitative parameters.
3) Evaluate technical capability such as: availability of parallel imaging, coil availability, acquisition time, flexibility in scan direction, flexibility in choice of resolution, and field of view (FoV). Compare technical capabilities to best MR practices.
4) Evaluate the possibilities to improve MRI sequences through modification of its source code. Explore options to improve diagnostic performance through independent image reconstruction of raw data generated by the sequence.
5) Assess the utility of the optimized MRI sequences/technology in the evaluation of normal and abnormal tissue structure and physiological

processes.
6) Evaluate the optimized MRI sequences/technology for new indications and applications.

### Study design

One evaluation study will be performed per sequence/technology. This studies will be single center observational diagnostic studies. We expect to analyze 10 MRI sequences/ technologies in 4 years. The maximum number of volunteers per study will be 50. A maximum of 500 volunteers will be included.

### Study burden and risks

Burden: MRI examination for maximum 90 minutes. Exposure to acoustic noise. Contrast media injection. Blood withdrawal (can be collected from intravenous access for contrast media injection). Risks: incidental findings. Allergy or shock due to contrast media injection.

## 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 subject (defined as a volunteer who is not referred to Erasmus MC with signs and symptoms of disease)
- At least 18 years old
- Signed informed consent

## Exclusion criteria

- Subjects with a typical contra-indication to an MRI exam.
- Subjects with metal implants.
- Subjects who have a documented allergy to MRI contrast media or a contra-indication for - contrast-media are eligible for MRI, but will not undergo contrast-enhanced MRI.
- Woman who are pregnant or lactating
- Having any physical or mental status that interferes with the informed consent procedure

# Study design

## Design

**Study type:** Observational invasive

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

## Recruitment

NL

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|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 02-02-2014 |
| Enrollment: | 500 |
| Type: | Anticipated |

# Ethics review

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| Approved WMO Date: | 01-05-2014 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 08-03-2018 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

# 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 | NL47429.078.13 |