MRI in the fast lane: MR-STAT

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26690

Source
Nationaal Trial Register

Brief title
MR-STAT

Health condition

one of the following neurological diseases: primary brain tumour, epilepsy, MS or ischemic stroke

Sponsors and support

Primary sponsor: UMC Utrecht and NWO
Source(s) of monetary or material Support: NWO and UMC Utrecht

Intervention

Outcome measures

Primary outcome

The primary objective of this clinical study is to assess image quality of MR-STAT-generated synthetic image data sets (e.g. synthetic T1-, T2-, PD-weighted, FLAIR) in patients with neurological diseases. Although preliminary results in healthy volunteers have shown MR-STAT is able to generate good quality MR images with clinically desired image contrast weightings, due to a lack of pathology these images have only been assessed for general quality, i.e. image contrast, (lack of) artefacts, etc. Patients in the current study will have a

variety of recognizable pathology on standard MRI, which enables not only general quality assessment but also assessment of the discriminative power of the (MR-STAT) synthetic data sets to differentiate pathology from healthy tissue.

Secondary outcome

The secondary objective of this study is to compare the MR-STAT-generated synthetic image data sets with those acquired individually according to standard clinical protocol – i.e. standard T1-weighted vs. synthetic T1-weighted images and so forth – to assess image quality of the synthetic images compared with gold standard.

Study description

Background summary

Rationale: A standard clinical MRI examination consists of several MRI sequences with different image contrast weightings, that together take at least 20 minutes to perform. This long acquisition time significantly reduces applicability of MRI in the acute setting and in patients prone to motion during the examination, including children. We have developed a new acquisition and post-processing technique – MR-STAT – which is able to synthesize image data sets with various clinically used contrast weightings, using only one 5-minute MRI sequence, thereby substantially reducing the acquisition time.
Objective: To assess image quality of MR-STAT-generated synthetic image data sets in patients with neurological diseases (primary objective), and compare image quality of these synthetic images with those acquired individually according to standard clinical protocol (gold standard; secondary objective).
Study design: Single-centre, cross-sectional study, conducted in the UMC Utrecht. MR-STAT imaging will be performed on a 3.0 tesla (3T) MRI platform in 10 healthy controls and 40 patients with varying neurological diseases, combined with standard MRI sequences of the brain as gold standard. Three observers will score all data while blinded to type of MRI technique. For the first objective, MR-STAT image data sets will be scored on overall image quality, image artefacts and visualization of major anatomical structures. For the second objective, MR-STAT images will be assessed with the standard clinical MR images in a side-to-side fashion, to compare image quality of the MR-STAT data sets with gold standard.
Study population: Adult patients with one of four of the following characteristic neurological diseases: primary brain tumour, epilepsy, multiple sclerosis (MS) and ischemic stroke. Per disease, 10 patients will be included. In addition, healthy volunteers without a history of neurological disease will be included.
Main study parameters/endpoints:
The main study parameters are image quality scores of the MR-STAT-generated image data sets (overall image quality, image artefacts, visualization of predefined anatomical structures).
Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Subjects will not benefit from this study. The risks associated with the study correspond to the general risks associated with a clinical MRI examination, such as temporary dizziness and claustrophobia. No contrast agent is needed.

Study objective

Since only one MRI sequence (5 min acquisition time) will be necessary to generate 3 (or even more) MR image datasets, the total acquisition time of MRI examinations can be strongly reduced, translating in a direct cost reduction, increased patient comfort and broader clinical applicability. Although the preliminary experiments in healthy volunteers are promising, how well the MR-STAT technique performs in patients with abnormalities on brain MRI is not clear yet. In the current study protocol, we aim to test our technique in a cohort of patients with neurological diseases.

Study design

Patients needs to undergo just one single MRI exam.

Intervention

All subjects will undergo a 3T MRI examination that includes the MR-STAT sequence as well as several ‘normal’ brain MRI sequences with image contrasts that can also be synthesized with the data from the MR-STAT sequence. Of note, these ‘normal’ sequences are not the same as the very high-resolution MRI sequences that are generally used in academic hospitals like the UMC Utrecht, but instead are
more comparable to standard MRI sequences for fast scanning or from non-academic hospitals. Therefore, the MR-STAT MRI examination should be seen as a separate examination that cannot and will not be combined
with possible clinically acquired MRI examinations. The total examination time will be approx. 45 minutes; this time frame includes the MR-STAT sequence (5 minutes), standard clinical brain MRI equences (20 minutes) as well as patching of the MR system (activating specialized software that changes basic scanner settings, which is mandatory for the MR-STAT sequence to run properly) and any unforeseen delays.

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a patient must meet the following criteria:
1) Age ≥ 18 years
2) Diagnosed with one of the following neurological diseases: primary brain tumour, epilepsy, MS or ischemic stroke
3) Previous imaging findings characteristic of particular neurological disease
4) Ability to lie supine in the MRI scanner for 45 minutes

Exclusion criteria

Patients will be excluded when meeting one of the following criteria:
a) Atypical imaging findings not characteristic for the neurological diagnosis
Exclusion criteria for the healthy volunteers are as follows:
b) History of any neurological disease
c) Refusal to be informed of clinically relevant incidental findings

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2019

Enrollment:	50
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	04-03-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48176
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8437
CCMO	NL69544.041.19
OMON	NL-OMON48176

Study results

Summary results

1) Sbrizzi, A., van der Heide, O., Cloos, M., van der Toorn, A., Hoogduin, H., Luijten, P. R., & van den Berg, C. A. (2018). Fast quantitative MRI as a nonlinear tomography problem. Magnetic resonance imaging, 46, 56-63.

2) van der Heide, O., Sbrizzi, A., Luijten, P. R., & van den Berg, C. A. (2019). High resolution in-vivo MR-STAT using a matrix-free and parallelized reconstruction algorithm. NMR Biomed, In press