MRI in the fast lane: MR-STAT

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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...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON48176

Source
ToetsingOnline

Brief title
MR-STAT

Condition

- Other condition
- Central nervous system vascular disorders

Synonym
Stroke; ischemic infarct

Health condition

Overige zenuwstelsel-aandoeningen: demyeliniserende aandoeningen (MS), neoplasmata en epilepsie

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,NWO Demonstrator grant 2018-2019 (A. Sbrizzi)

Intervention

Keyword: MRI

Outcome measures

Primary outcome

The main study parameter will be the image quality scores of the

MR-STAT-generated image data sets with regard to overall image quality, image

artifacts, and visualization of several predefined anatomical structures; these

scores will be compared with those of the standard MRI data sets.

Secondary outcome

The secondary study parameter will be the image quality of the

MR-STAT-generated image data sets compared with the standard MRI data sets,

assessed in a side-by-side fashion.

Study description

Background summary

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.

Study 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-center, 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 artifacts 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 burden and risks

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.

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

In order to be eligible to participate in this study, a patient must meet the following criteria:
• Age >= 18 years
• Diagnosed with one of the following neurological diseases: primary brain tumor, epilepsy, MS or ischemic stroke
• Previous imaging findings characteristic of particular neurological disease
• Ability to lie supine in the MRI scanner for 45 minutesAlthough not an inclusion criterion, care is taken to select those patients that are already scheduled for a standard clinical follow-up MRI examination within the next 4 months, thereby limiting patient burden by providing the option to combine both study- and clinical MRI examination on the same day.Inclusion criteria for healthy volunteers are the following:
• Age >= 18 years
• No history of neurological diseases

Exclusion criteria

Patients will be excluded when meeting one of the following criteria:
• Atypical imaging findings not characteristic for the neurological diagnosisExclusion criteria for the healthy volunteers are as follows:
• History of any neurological disease

Study design

Design

Study type: Observational invasive

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-11-2019
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	19-06-2019
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	20-12-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	13-05-2022
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26690
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL69544.041.19
OMON	NL-OMON26690