Test-Retest of MR Fingerprinting technology for improved visualization and quantification of tissue and organs in healthy volunteers and brain tumor patients

Published: 18-05-2018
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To optimise, test and evaluate new and modified MRI sequences and technology under a test-retest scheme. To validate new sequences in patients in order to reduce MRI protocols in the future.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Observational invasive

Summary

ID

NL-OMON48926

Source
ToetsingOnline

Brief title
MR Fingerprintig Sequences Validation

Condition

- Joint disorders
- Metastases
- Central nervous system infections and inflammations

Synonym
tissues and organs

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,GE Company

Intervention

Keyword: Fingerprinting, MRI, Quantification, Visualization

Outcome measures

Primary outcome

Healthy volunteers:

Parameters of image quality: artefacts, signal to noise, contrast to noise,

reproducibility, accuracy.

Patients:

Quantitative MR (T1, T2, PD).

Secondary outcome

NA

Study description

Background summary

New or modified MRI sequences/technologies has to be evaluated in healthy volunteers and patients in order to assess the additional value of these sequences/technologies in the visualisation and quantification of tissues and organs.

Study objective

To optimise, test and evaluate new and modified MRI sequences and technology under a test-retest scheme. To validate new sequences in patients in order to

reduce MRI protocols in the future.

Study design

Observational diagnostic study.

Study burden and risks

Burden: MRI examination for maximum 60 minutes in healthy volunteers and 10 minutes in patients. Exposure to acoustic noise. Risks: incidental findings.

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 subjects:
- Healthy subject (defined as a volunteer who is not referred to Erasmus MC with signs and symptoms of disease)
- At least 18 years old and not older than 50 years old.
- Signed informed consent

Patients:
- Patients with brain tumor with previous conventional scan and referred to conventional treatment.
- Adults
- Signed informed consent

Exclusion criteria

Healthy subjects:
- Subjects with a typical contra-indication to an MRI exam.
- Subjects with metal implants.
- Woman who are pregnant or lactating
- Having any physical or mental status that interferes with the informed consent procedure

Patients:
- Subjects with a typical contra-indication to an MRI exam.
- Subjects with metal implants.
- 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

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-01-2019
Enrollment:	54
Type:	Actual

Ethics review

Approved WMO Date:	18-05-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-11-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-07-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-10-2019
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	NL64907.078.18