Test-retest validation of quantitative MRI in healthy volunteers

Published: 29-09-2021
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The primary objective is to determine the repeatability of quantitative MRI measures in the healthy tissue on a diagnostic MRI system or hybrid MRI-linac system.

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

Summary

ID

NL-OMON49913

Source
ToetsingOnline

Brief title
test-retest MRI in healthy volunteers

Condition

- Other condition

Synonym
healthy volunteers for control of diagnostics in cancer patients, none

Health condition

het betreft gezonde vrijwilligers

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: eigen RT afdeling

Intervention

Keyword: MRI, MR-linac, radiotherapy

Outcome measures

Primary outcome

The main study parameter is the repeatability coefficient (within-coefficient

of variance) between the qMRI values measured during the test and retest

Secondary outcome

not applicable

Study description

Background summary

Quantitative magnetic resonance imaging (qMRI) biomarkers are used to monitor and predict short and long-term treatment response in cancer patients. qMRI techniques can either depict radiation-induced changes to the tumor and/or to the surrounding healthy tissue. To develop qMRI techniques, it is necessary to design scanning protocols for a particular anatomy and to evaluate the precision of the measurements taken. For this, the repeatability of the measurement needs to be established in a test-retest study. Prior to applying these techniques in patients, the repeatability can be determined in cohorts of healthy volunteers. Therefore, in this study, the repeatability of qMRI measures will be investigated in cohorts of healthy volunteers, in order to determine a baseline for qMRI biomarkers. To assess repeatability, a test-retest study will be performed on the same MRI scanner.

Study objective

The primary objective is to determine the repeatability of quantitative MRI measures in the healthy tissue on a diagnostic MRI system or hybrid MRI-linac system.

Study design

Healthy volunteers will receive two quantitative MRI exams on the same system within a couple of weeks, to access repeatability. MRI techniques that will be tested in this protocol include, but are not limited to: diffusion-weighted

MRI, mDIXON MRI and T1/T2 mapping. Techniques that require administration of contrast agents are excluded. MRI sessions will be performed outside of clinical time.

Study burden and risks

The healthy volunteers will be schedule for two 1h MRI scanning sessions, with a maximum duration of one hour each. The second MRI scanning session will be within a month of the first one.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

• Volunteer, age >= 18 years, willing to be scanned two times within a couple of

weeks apart.
• Ability to understand and the willingness to sign a written informed consent and a safety screening document

Exclusion criteria

• Contra*indications for an MRI examination.
• Pregnancy.
• Claustrophobia.
• Any clinically significant medical condition which, in the opinion of the researchers, makes it undesirable to participate in the study or which could jeopardize compliance with study requirements or severe psychiatric illness/social situation.
• refusal to be informed about incidental findings on the MRI.
Additional in- and exclusion criteria may apply to specific techniques and are listed in the technique specific study manuals provided. When these criteria differ from those listed here, the technique specific in/exclusion criteria will take precedence

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-11-2021
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	29-09-2021
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	05-05-2023
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

No registrations found.

In other registers

Register	ID
CCMO	NL78118.031.21