Test-retest validation of quantitative MRI

Published: 23-12-2021
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The primary objective is to determine the repeatability of quantitative MRI measures on either a diagnostic MRI system or MRL.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON50975

Source
ToetsingOnline

Brief title
test-retest MRI

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
cancer, malignancy

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 quantitative MRI values measured during the test and

retest.

Secondary outcome

NA

Study description

Background summary

To determine the suitability of the quantitative MRI techniques for response measurements, the first step is to determine the accuracy of the quatitative measurements in patients. Therefore a retest has tot be executed.

Study objective

The primary objective is to determine the repeatability of quantitative MRI measures on either a diagnostic MRI system or MRL.

Study design

All patients who receive an MRI exam for radiotherapy treatment simulation and/or who will be treated on the MRL

Study burden and risks

The patients will receive an additional MRI exam (re-test), which will be scheduled on a day on which one has to be in the hospital for another appointment. This additional MRI exam may last up to 30 minutes. Earlier on, the standaard MRI (as preparation of the radiation treatment) will be extended for 10 minutes.

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

- age >= 18 years, who receive an MRI for preparation of their treatment with radiotherapy and/or who receive radiation treatment on the MRL
- WHO performance status 0-2
- ability to understand and willingness to sign a written informed consent

Exclusion criteria

- Contra-indications for an MRI examination
- Pregnancy
- Claustrophobia
- Over 140 kg and/or a body with over 60 cm

- Patients with any other clinically significant medical condition which, in the opinion of the treating physician, makes it undesirable fot the patient to participate in the stydy or which jeopardize compliance with study requirements or severe psychiatric illness/social situation

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):	24-04-2022
Enrollment:	208
Type:	Actual

Ethics review

Approved WMO

Date:	23-12-2021
Application type:	First submission
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	NL78023.031.21