Healthy volunteer studies for development of imaging techniques for motion management in MR-guided adaptive radiotherapy

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Development of new imaging techniques for MR-guided motion management in the presence of respiratory motion

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Upper respiratory tract disorders (excl infections)
Study type	Observational non invasive

Summary

ID

NL-OMON48889

Source
ToetsingOnline

Brief title
4D-MRGART

Condition

- Upper respiratory tract disorders (excl infections)

Synonym
MRI, organ motion management

Research involving
Human

Sponsors and support

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

Intervention

Keyword: adaptive radiotherapy, imaging techniques, MRI, MRI-guided radiotherapy

Outcome measures

Primary outcome

Image quality of investigated MR sequences. Scan time and delay. Image

registration accuracy

Secondary outcome

not applicable

Study description

Background summary

With the MR Linac, we can visualize tumors before and even during irradiation and apply corrections for (respiratory) motion and thus provide accurate treatment in the future. It is, however, challenging to make good quality images in the presence of respiratory movement. Therefore, the development of new imaging techniques, including 4D-MRI and dynamic MRI, is needed. These MRI scans will be tested among others for their fitness for motion correction before and during treatment

Study objective

Development of new imaging techniques for MR-guided motion management in the presence of respiratory motion

Study design

feasibility study with healthy volunteers

Study burden and risks

MRI is considered a very safe and painless medical imaging procedure and there is no known health risk associated with scanning when appropriate precautions are taken. The magnetic field strength (1.5 Tesla) is routinely used clinically without harm.

A MRI examination will not last longer than 1 hour.

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 volunteers without known malignancies or other pathology

Exclusion criteria

- Contra*indications for a MRI examination
- Claustrophobia

• Subjects >140 kg and/or a circumference > 60 cm

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):	27-11-2017
Enrollment:	250
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	24-08-2017
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	14-12-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	29-10-2019
Application type:	Amendment

Review commission:	METC NedMec
Approved WMO Date:	30-01-2025
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	NL62311.031.17