MRI protocol development for MR-linac

Published: 08-02-2017
Last updated: 15-04-2024

To optimize MRI protocols and processing techniques required for MRI guided radiotherapy on the MR-linac measured as signal to noise ratio, contrast, and acquisition time.

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

Summary

ID

NL-OMON55710

Source
ToetsingOnline

Brief title
MR-linac

Condition

- Other condition

Synonym
protocol development; MRI protocol optimization for MR-linac

Health condition

Geen specifieke aandoening te benoemen. De ontwikkelde protocollen en beeldverwerkingstechnieken kunnen voor verschillende aandoeningen worden gebruikt.

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: MR-linac, volunteer

Outcome measures

Primary outcome

The optimized MRI protocols and processing techniques required for MRI guided radiotherapy on the MR linac measured as signal to noise ratio, contrast, and acquisition time.

Secondary outcome

na

Study description

Background summary

The MR-linac (MRL) is a hybrid machine which enables true image guided radiotherapy. Image guidance of radiation treatment minimizes the uncertainties about the location and shape of the tumor and surrounding organs at risk. Therefore, margins to ensure tumor coverage can be reduced. This gives the opportunity for dose escalation to the tumor and/or decrease the number of fractions, which can result in reduction of the organs at risk dose, decreased radiation-induced toxicity and better quality of life.
MR imaging in combination with radiation delivery requires technical adjustments to both the MRI and the linac hard-ware to prevent interference of the magnet on the linac and vice versa. For imaging, this means that we have to deal with reduced gradient strength, which demands optimization of the acquisition protocols. For the development of optimal MRI guided radiotherapy strategies, images have to be acquired on the MR-linac. The hard-ware of the MRI scanner installed in de MR-linac is different from a stand-alone MRI. Therefore, scans have to be optimized and imaging strategies have to be tested. During a treatment on the MR-linac MR images will be required in different stages of the treatment: the pre-beam, beam-on and post-beam stage. In the pre-beam phase, target definition, i.e. contouring (segmentation) of the tumor and organs at risk, dose calculation, motion characterization is required. In the beam-on phase motion target tracking and dose accumulation is performed, while in the post-beam phase evaluation of the radiation treatment can be tested. The current application deals with the pre-beam stage only.

Automatic segmentation of tumor and organs at risk needs images with a proper contrast and signal to noise ration. In motion tracking, the challenge is to image 3D volumes at a rate that is sufficient to track the tumor or gate the dose delivery. Also for dose accumulation, rapid imaging is needed. Additionally, the images need a high geometric accuracy. In the post beam imaging, quantitative imaging will be used, that needs optimization on this new hard-ware.
At this stage, several target regions have been defined for treatment development on the MR-linac. The tumor sites consist of: bone metastases, metastatic lymph nodes, rectum, prostate, esophagus, breast, pancreas, cervix, brain, head and neck, lung. For all these reasons it*s essential to optimize the dedicated scanning and image processing protocols for MR-linac.

Study objective

To optimize MRI protocols and processing techniques required for MRI guided radiotherapy on the MR-linac measured as signal to noise ratio, contrast, and acquisition time.

Study design

an observational study.

Study burden and risks

No benefits are expected for the volunteers.
No risks are known for healthy volunteers or patients undergoing MRI when they are screened according to the MRI safety criteria. Participants will be scanned during 45 to 90 minutes. A risk for subjects may be the finding of an unexpected abnormality.
The sequences needed to visualize organs at risk will be tested on healthy volunteers. Patients will only be asked if visualization of the tumor has to be tested. Only patients with a WHO performance status of <= 2 will be asked. Patient*s standard treatment will not be affected by the participation in this study.
The study will result in dedicated MRI scanning procedures and image processing techniques for patients to be treated on the MR-linac.

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 subject must meet all of the following criteria:, - >= 18 years
- Capable and prepared to sign informed consent
- Healthy volunteers or cancer patients who will be or are treated at the radiotherapy department, or patients with cancer at a stage or at a site that is not routinely treated with radiotherapy, where the aim is that future patients with a similar tumor stage or tumor site might be treated on the MRL.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:, - Contraindication for MRI scanning as listed in screening form
- Neurological or psychiatric diagnosis
- MRI contraindications such as (possible) pregnancy and metal or electronic implants not compatible with MRI
- Refusal of subjects to be informed of chance findings possibly relevant to their health

- In case study participation would interfere with regular treatment

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):	09-02-2017
Enrollment:	900
Type:	Actual

Ethics review

Approved WMO Date:	08-02-2017
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	07-06-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	07-02-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	24-11-2021
Application type:	Amendment

Review commission:	METC NedMec
Approved WMO Date:	30-01-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL59820.041.17