The UMBRELLA Study - MRI protocol development for MRI for MR-guided radiotherapy on the MR-Linac

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Goal of the UMBRELLA Study is the optimization of existing MRI protocols and processing techniques required for MRI guided radiation treatment on the Marlin system (MRI of the MR-Linac) and diagnostic MRI scanners in the radiology department needed...

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

Summary

ID

NL-OMON51088

Source
ToetsingOnline

Brief title
UMBRELLA

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
Cancer, oncology

Research involving
Human

Sponsors and support

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

Intervention

Keyword: MRI, MR-Linac, Radiotherapy

Outcome measures

Primary outcome

To optimize MRI protocols and processing techniques required for MRI guided radiation treatment on the Marlin system and the clinically used MR scanner of the Department of Medical Imaging estimated based on signal to noise ratio, contrast to noise and acquisition time.

Secondary outcome

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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, motion 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 a decrease in the number of fractions, which can result in improved tumor control, 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 hardware to prevent interference of the magnet on the linac and vice versa.
The hardware of the MRI scanner installed in de MR-Linac is different from a stand-alone (diagnostic) MRI itself. Therefore, scans have to be optimized and imaging strategies have to be validated for the MRL. Technically, this means that we have to deal with reduced gradient strength, which demands different optimization of the acquisition protocols when compared to diagnostic scanners.
In addition, MRI guided radiotherapy on the MRLinac has additional requirements on the images acquired for treatment planning on the diagnostic MRI compared to the scans already used within the radiotherapy department, such as a large FOV fully 3D acquisition large volume with a high geometric fidelity.

For the development of optimal MRI guided radiotherapy strategies, images have to be acquired both on the MR-Linac and diagnostic MRI. 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 and 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. Automatic segmentation of tumor and organs at risk needs images with a proper contrast and signal to noise ratio. 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. Additionally, the images need a high geometric accuracy.
At this stage, several target regions have been defined for treatment development on the MR-Linac [6-8]. The tumor sites consist among others of: oligo lymph node metastases, rectum, prostate, esophagus, bladder, breast, pancreas, cervix, head and neck, lung, liver metastases and primary liver tumors, adrenal gland oligo metastases, kidney, endometrium carcinoma, anal canal tumors. For all these
regions it is essential to optimize the dedicated scanning and image processing protocols for the MR-Linac.

Study objective

Goal of the UMBRELLA Study is the optimization of existing MRI protocols and processing techniques required for MRI guided radiation treatment on the Marlin system (MRI of the MR-Linac) and diagnostic MRI scanners in the radiology department needed for treatment preparation.
The initial scientific focus of the MRI protocol development project is to optimize MRI techniques and processing techniques that will enable MR guided radiation treatment. The current project will encompass the optimization of several techniques such as: methods for improved target definition and treatment planning, and evaluation for MR guided radiotherapy. Since the underlying technical problems are comparable but not equal for all tumor sites, the development of the techniques will be performed parallel to each other. From the technical viewpoint, the goals of this study are to acquire geometrically accurate MR imaging with a good contrast to noise ratio to be able to contour targets and organs at risk accurately within a limited amount of time.

Study design

This is an observational study in which available clinical MRI acquisition software and protocols for radiotherapy are tested, in which MRI acquisition software and protocols are optimized or new protocols are generated for MRI*s at the Department of Radiology to prepare for new radiotherapy indications and in which processing techniques required for MRI guided radiation treatment are

evaluated.

Adjustment of parameters of the acquisition software on the Marlin system will be rather limited. The available acquisition software can be tested and the preferred contrast can be chosen for visualization of tumor and organs at risk at the different tumor regions.
Planning MRI protocols for the visualization of tumor tissue and organs at risk on the MR scanners of the Department of Radiology have to be optimized or even generated. Differences in SNR, resolution, geometric accuracy and image artefacts will be explored and reviewed in order to assess whether the protocols are adequate for application for treatment planning on an MR-Linac. Assessed MRI data will also be used to develop and test processing techniques which are needed to improve the use of the MR-Linac as a safe treatment option for future cancer patients. This includes contour and dose plan generation i.e. by transfer of contours from MR images acquired in the pre-treatment simulation phase to MR images acquired on the Marlin.

The number of subjects per study required to finalize a particular protocol may vary depending on the technical challenges that have to be solved for that particular acquisition software or protocol. Patients will only be included if tumor visualization is required. Both patients and volunteers can be asked to undergo an MRI on the Marlin system, on the diagnostic MR scanner at the Department of Radiology for treatment simulation, or both.
Image quality and/or the performance of quantitative imaging methods is assessed by clinicians (radiation oncologists, radiologists and others) and MR physicists. Special attention will be paid to geometric accuracy. If necessary, an equivalent MR image will be acquired on the normal diagnostic MR scanner at the Department of Medical Imaging for image quality assessment. This in order to detect the origin of artifacts or limited signal-to-noise ratio and to further optimize the protocols.
Most artifacts in MRI can be resolved by means of tuning of acquisition parameters. Optimization of acquisition parameters is performed in-vivo by systematically changing the MR parameters involved. Such optimization procedures should be performed in several subjects to obtain robust settings that are subject independent and preserve geometric accuracy.

Study burden and risks

Although not the aim of the study, medical imaging of this study may reveal unexpected or incidental findings. Beforehand, subjects are informed that this may happen and informed about the procedure following on these incidental findings. The aim of this procedure is to inform subjects if they have potentially clinically relevant findings so that further investigations can be initiated. A statement of this procedure is part of the ICF. If the potential subject does not agree with this procedure, he/she cannot participate in this study. A Standard Operating Procedure is in place (see SOP Nevenbevindingen medische beeldvorming

For some participating patients a contrast agent will be injected. This will only be done after a medical doctor has estimated the risk and burden as low for the patient based on the available kidneyfunction and information about allergies. Contrast agents will not be used for healthy volunteers.

Contacts

Public
Radboud Universitair Medisch Centrum

Geert Grooteplein 32
Nijmegen 6500 HB
NL
Scientific
Radboud Universitair Medisch Centrum

Geert Grooteplein 32
Nijmegen 6500 HB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

>= 18 years
Capable and prepared to sign informed consent
Healthy volunteers or cancer patients

Exclusion criteria

Contraindication for MRI scanning as listed in screening form
Neurological or psychiatric diagnosis making it impossible to remain in the same position for the whole duration of the MRI examination.
Refusal of subjects to be informed of chance findings possibly relevant to their health
In the case that study participation would interfere with regular treatment

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-10-2021
Enrollment:	300
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	02-06-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date:	21-02-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL76690.091.21

Study results

Results posted: 10-02-2022

First publication
01-01-1900