MR-only workflow in radiotherapy for patients with prostate cancer and patients with rectal cancer.

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Primary objective:To investigate whether MR-only radiotherapy in prostate and rectal cancer patients is at least non-inferior in terms of position verification performed by a registration between the pCT and CBCT instead of the CT.Secondary...

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

Summary

ID

NL-OMON48921

Source
ToetsingOnline

Brief title
MR-only workflow for in radiotherapy.

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
prostate cancer, rectal cancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: MR-only workflow, prostate cancer, radiotherapy, rectal cancer

Outcome measures

Primary outcome

In each of the 29 prostate cancer patients, a registration of fiducials will be made for each of the 35 treatment fractions. In each of the 29 rectal cancer patients, a registration based on bony anatomy will be made and the best fitting plan will be selected from the LOP for each of the 25 fractions. Each registration consists of a vector in x-, y-, and z-direction. These will be noted and the standard deviation of all the registration vectors per patient will be calculated. We will refer to this parameter as the variation in registrations per patient.

In case a patient is not able to complete his treatment, he/she will be replaced by another patient.

We will perform a noninferiority test (* = 0.05, 1-* = 0.80) on both the variation of the registrations on fiducials in prostate patients and the variation of the registrations based on bony anatomy in rectal patients. The null hypothesis is that the standard deviation of the variation in the MR-only workflow is higher and thus inferior to the conventional workflow.

We expect a common standard deviation of 0.8 mm for the registration on fiducials in prostate cancer patients. We expect a common standard deviation of 0.55 mm for the registration based on bony anatomy in rectum cancer patients.

We reject the null hypothesis at a limit difference of 2/3 of the expected standard deviation, thus 0.53 mm in the prostate cancer patients and 0.37 mm in

the rectal cancer patients.

Secondary outcome

The secondary parameter is the feasibility of the plan selection for the rectal cancer patients. This evaluation is qualitative. The plan selected per fraction in the MR-only workflow should be the same as in the conventional workflow. Also, the RTT should experience this as equally difficult. This will be qualified by the RTT*s from the research team as they perform the simulated MR-only workflow. These RTT*s have extended clinical experience in plan selection. They will report parameters such as time needed and certainty in decision making.

Study description

Background summary

Radiation treatment starts with the imaging of the patient on a CT scanner. This CT scan will be used throughout the treatment. The CT scan is first used to determine and delineate the target volume and the organs at risk (OAR) (sometimes supported by other imaging modalities), secondly to calculate the dose of the treatment plan, and finally it is used as a reference for position verification before each treatment fraction. For the latter, a cone-beam CT (CBCT) is made of the patient on the treatment table. Position verification is then performed by a registration between the CT and the CBCT.
Since MR images exceed the CT image in soft-tissue contrast, it is standard procedure in patients with prostate cancer and in some patients with rectal cancer to use both a CT image and an MR image for delineation. There are several disadvantages of this procedure: first a patient must undergo two separate scans. Furthermore, as the scans are made on different machines and with a timespan of at least an hour, there will be a difference in the patient*s anatomy and positioning between the scans. This introduces errors in the delineation of the target volume and OAR*s as the images are both used but contain conflicting information because of the imperfect registration between them. The errors in the delineations need to be accounted for, typically by introducing a treatment margin, which increases the volume of irradiated healthy normal tissue.

With special MR imaging techniques it is now possible to make a so called *pseudo CT* (pCT) . The pCT is proven to be suitable for dose calculations in treatment planning. The pCT may also be suitable for position verification by a registration between the pCT and CBCT. With the use of this MR technique, the CT may no longer be needed and patients can be treated using only MR images: the MR-only workflow. In this study we would like to investigate whether the MR-only workflow can be clinically introduced in prostate and rectal cancer patients with at least noninferiority in position verification by a registration between pCT and CBCT. Therefore, we would like to compare the conventional CT-based radiation treatment with an MR-only treatment simulation.

Study objective

Primary objective:
To investigate whether MR-only radiotherapy in prostate and rectal cancer patients is at least non-inferior in terms of position verification performed by a registration between the pCT and CBCT instead of the CT.

Secondary objective:
Feasibility of plan selection using the pCT instead of the CT for radiotherapy in rectal cancer patients. This evaluation is qualitative. The plan selected per fraction in the MR-only workflow should be the same as in the conventional workflow. Also, the RTT should experience this as equally difficult.

Study design

The study is a prospective observational cohort study. To generate the pCT, an extra MR sequence is added to the standard scan protocol, prolonging the scan time by 10 minutes. The pCT will be used to simulate an MR-only radiotherapy of the patient. The actual treatment of the patient is according to the conventional clinical protocol.

Study burden and risks

An MR sequence is added to the normal MR scan protocol of the patients. This will prolong the standard MR scan time of 30 to 45 minutes by 10 minutes. Since MR imaging does not impose any ionizing radiation burden, patients are not susceptible to radiation hazards or any other added risks. Furthermore, patients are free to halt the procedure and withdraw from the extra MR sequence at any time. Patients will not benefit from participation in this study.
It is only possible to investigate the differences between the conventional and simulated MR-only treatment by comparing registrations between CT and CBCT*s with registrations between pCT and CBCT*s. The CT scan and CBCT scans impose ionizing radiation hazard, which are justified in context of the patient*s radiation treatment. The acquisition of the pCT from MR scans does not impose ionizing radiation burden. Therefore, our study design is the only way to

compare the two workflows without imposing patients to ionizing radiation burden. The risk on side effects of the procedure are minimal (see risk assessment form). The study does not include minors or incapacitated adults.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Patients have to be older than 18 years.
* They have to be diagnosed with prostate or rectal cancer and willing to undergo a treatment with radiotherapy with curative intent at the AMC.

Exclusion criteria

* Incapacitated patients.
* Any 3T MRI contra-indications stated by the AMC MRI safety committee (see appendix A)
* Patients with one or two hip prosthesis.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-09-2018
Enrollment:	58
Type:	Actual

Ethics review

Approved WMO

Date:	21-08-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL65414.018.18