MRI study to prepare for adaptive MRI-guided radiation of prostate carcinoma

Gepubliceerd: 02-01-2021 Laatst bijgewerkt: 13-12-2022

The aim of the study is to investigate the effect of magnetic resonance (MR) based online adaptive radiotherapy (RT) for treatment of low to intermediate risk localized prostate carcinoma (PCa) on the radiotherapy dose on the prostate and organs at...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20274

Bron
NTR

Verkorte titel
N/A

Aandoening

prostate carcinoma

Ondersteuning

Primaire sponsor: Radiotherapiegroep
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

o D2cc of the rectum (the minimum dose in 2cc of the rectum receiving the highest dose) and the mean difference in D2cc between the traditional and the online adaptive protocol.

o D2cc of the bladder (the minimum dose in 2cc of the bladder receiving the highest dose) and the mean difference in D2cc between the traditional and the online adaptive protocol.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: MRI accelerator systems combine a hybrid MRI and radiotherapy system (i.e. a linear accelerator). MRI based RT enables the ability to perform daily adaptive re-planning on the anatomy of the day. Daily adaptive re-planning could ensure more effective tumor targeting while sparing the surrounding tissue as much as possible. Better targeting will possibly enable diminishing radiotherapy margins, reducing toxicity and enabling future dose escalation to increase tumor control rates.
Objective: The aim of the study is to investigate the effect of magnetic resonance (MR) based online adaptive radiotherapy (RT) for treatment of low to intermediate risk localized prostate carcinoma (PCa) on the radiotherapy dose on the prostate and organs at risk (OAR) compared to the current standard. The current standard is gold marker based RT with position verification on CBCT.
Study design: Prospective imaging (MRI) study.
Study population: Patients with low and intermediate risk prostate cancer treated by external beam radiotherapy at the RTG, eligible for MRI scans.
Intervention: This is an MRI-imaging study. In total 5 additional MRI’s will be acquired for each of 10 patients treated for low or intermediate risk prostate cancer by standard external beam radiotherapy.
Main study parameters/endpoints: Comparison of daily simulated dose to organs at risk (OAR) and target volume (=prostate) for extremely hypofractionated radiotherapy (5x7.25Gy) for CBCT based RT versus MRL based RT.

Doel van het onderzoek

The aim of the study is to investigate the effect of magnetic resonance (MR) based online adaptive radiotherapy (RT) for treatment of low to intermediate risk localized prostate carcinoma (PCa) on the radiotherapy dose on the prostate and organs at risk (OAR) compared to the current standard. The current standard is gold marker based RT with position verification on CBCT.

Onderzoeksopzet

The study is a radiotherapy pilot planning study simulating the MR based RT dose on the daily MRI-anatomy. Patients treated by standard EBRT in 5 fractions within Radiotherapiegroep (RTG) (Deventer, the Netherlands) for biopsy confirmed low to intermediate risk localized PCa are asked to undergo 5 additional MRI’s (= study procedure) for the present dose planning study. Patients will be recruited and asked for written informed consent by their radiation oncologist at RTG. If interested, they are contacted by the

researcher and asked for informed consent after receiving all information. There are no follow up time points included in this study.

Onderzoeksproduct en/of interventie

The study is a radiotherapy pilot planning study simulating the MR based RT dose on the daily MRI-anatomy. Patients treated by standard EBRT in 5 fractions within Radiotherapiegroep (RTG) (Deventer, the Netherlands) for biopsy confirmed low to intermediate risk localized PCa are asked to undergo 5 additional MRI's (= study procedure) for the present dose planning study. Patients will be recruited and asked for written informed consent by their radiation oncologist at RTG. If interested, they are contacted by the researcher and asked for informed consent after receiving all information. There are no follow up time points included in this study.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
• Patients with a low to intermediate risk localized PCa confirmed by biopsy and scheduled for curative intent EBRT at RTG;
• ≥ 18 years;

• No transurethral resection of the prostate (TURP) in the last 3 months;
• No anorectal surgery in the past or other situations in which the anorectal anatomy is abnormal;
• No hip prosthesis;
• Meet all MRI safety criteria for MRI at 1.5T according to the protocol of the department of Radiology;
• Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• V18 years;
• Transurethral resection of the prostate (TURP) in the last 3 months;
• Anorectal surgery in the past or other situations in which the anorectal anatomy is abnormal;
• Hip prosthesis;
• No compliance with all MRI safety criteria for MRI at 1.5T according to the protocol of the department of Radiology;
• No written informed consent.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2021
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	02-01-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9148
Ander register	CMO Regio Arnhem-Nijmegen : Dossiernummer: 2020-6995 NL-nummer: NL74822.091.20

Resultaten