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

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Pending |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON20274

**Source**
Nationaal Trial Register

**Brief title**
N/A

**Health condition**

prostate carcinoma

### Sponsors and support

**Primary sponsor:** Radiotherapiegroep
**Source(s) of monetary or material Support:** None

### Intervention

### Outcome measures

**Primary outcome**

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.

### Secondary outcome

o D99% and D95% CTV prostate
o D50% of the rectum and bladder
o Dmean of the anal canal
o D2cc of the small bowel
Dx% is the minimum dose to the highest irradiated x% volume of the volume of interest.

## Study description

### Background summary

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.

### Study 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

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.

**Intervention**

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.

# Contacts

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# Eligibility criteria

## Inclusion criteria

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.

### Exclusion criteria

• 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.

## Study design

### Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Other |
| Allocation: | N/A: single arm study |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-02-2021 |
| Enrollment: | 10 |
| Type: | Anticipated |

### IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion

| | |
|---|---|
| Date: | 02-01-2021 |
| Application type: | First submission |

## 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 |
|---|---|
| NTR-new | NL9148 |
| Other | CMO Regio Arnhem-Nijmegen : Dossiernummer: 2020-6995 NL-nummer: NL74822.091.20 |

## Study results