Stereotactic MR-guided Adaptive Radiation Therapy (SMART) for localized prostate cancer; a phase II study

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Renal and urinary tract neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON42880

Source
ToetsingOnline

Brief title
SMART localized prostate cancer

Condition

- Renal and urinary tract neoplasms malignant and unspecified

Synonym
carcinoma of the prostate, prostate cancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: MR-guided, prostate cancer, radiotherapy, stereotactic

Outcome measures

Primary outcome

The main objective of this phase II observational study is to investigate the early and early-delayed toxicity, special attention for GI symptoms, GU symptoms and sexual symptoms, that is observed in the first year following treatment at 6 weeks, 3, 6, 9 and 12 months.

Secondary outcome

The secondary objective of this study will be to investigate the dosimetric benefit of the adaptive part of SMART in patients with localized prostate cancer. Also Quality of life (QoL) will be monitored using the EORTC QoL core questionnaire (QLQ-C30) in combination with the QLQ Prostate Cancer module (QLQ-PR25).

Study description

Background summary

External beam radiotherapy (EBRT) is the treatment of choice in a substantial proportion of patients with localized prostate cancer (cT1c-T3N0M0).
Total doses and dosage per fraction plays an important role in the treatment of prostate cancer and the side effects of treatment. Several studies have proven these hypofractionated schemes to be equally efficient and tolerated as well as conventionally fractionated treatments, with the advantage that treatment can be delivered within two weeks [King et al, Radiother Oncol, 2013, Katz et al, Front Oncol, 2014, Henderson et al, Clin Oncol, 2015].

The clinical introduction of stereotactic MRI-guided adaptive radiation therapy (SMART) using the MRIdian treatment machine will enable visualisation of target volume and adjacent normal organs such as the rectum and bladder prior to- and

during treatment delivery. Online imaging allows to deliver *gated* treatment, enabling the use of small uncertainty margins, which can potentially limit clinical toxicity. One further advantage of the SMART approach for prostate cancer is the ability to perform adaptive treatment planning for each delivered fraction. This means that the original treatment plan can be optimized immediately prior to treatment delivery, especially optimized with respect to the position and size of the adjacent normal organs such as the rectum and bladder.

Study objective

The main objective of this phase II observational study is to investigate the early and early-delayed toxicity in 100 patients with localized prostate cancer (cT1c-T3bN0M0) that is observed in the first year following after stereotactic MRI-guided adaptive radiation therapy (SMART) using the MRIdian treatment machine of the adjacent normal organs, after daily adapting the treatment plan before every fraction on the anatomy of that day.

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Study design

The study is a prospective phase II observational trial

Study burden and risks

This novel SMART approach could set a new standard of care for patients with localized prostate cancer by limiting radiation doses to surrounding normal organs and thereby potentially radiation-induced toxicity. Also, implantation of gold markers would become unnecessary using MR-guided *gated* radiotherapy. Disadvantages for patients include the need to be positioned within the MRI bore during radiation delivery, and a prolonged time per treatment fraction (estimated at 30 minutes per fraction), which has to be weighed against the use of a total of only five fractions. As the radiation fractionation scheme that is used in this study has been evaluated in prior trials, no further patient-related risks are anticipated.

Patients will be followed-up with the frequency according to Dutch guidelines for localized prostate cancer.The extra time for filling in the questionnaires will be around 5-10 minutes.

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

- Age of 18 years or older
- WHO performance score 0-2
- Biopsy proven adenocarcinoma of the prostate
- Gleason * 6
- Prostate volume * 90 cc on TRUS
- T-stage: cT1c-T3b (on MRI and/or endorectal ultrasound)
- All patients should be able to undergo MRI scans
- No evidence of lymph node or distant metastases on radiological staging
- The multidisciplinary team advised external beam radiotherapy treatment
- IPSS (International Prostate Symptoms Score) *19
- Previous TURP is allowed provided there is at least 8 weeks interval with radiotherapy
- The administration of concomitant hormonal therapy is allowed

- Ability to provide written informed consent
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Exclusion criteria

- Previous irradiation in the pelvic region
- Contra-indications for MRI (see appendix X)

Study design

Design

Study phase:	2
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-08-2016
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	27-07-2016
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	NL57289.029.16