Feasibility of MRI guided focal high-dose-rate brachytherapy for localized prostate cancer

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To assess toxicity of MRI guided high-dose-rate focal brachytherapy as monotherapy for favourable risk prostate cancer. As secondary objectives, technical feasibility, quality of life and biochemical free survival will be determined.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Reproductive neoplasms male malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON47892

Source
ToetsingOnline

Brief title
Feasibility of MRI guided focal HDR-BT for localized prostate cancer

Condition

- Reproductive neoplasms male malignant and unspecified
- Male genital tract therapeutic procedures

Synonym
localized prostate carcinoma, prostate cancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: brachytherapy, high-dose-rate, localized prostate cancer, MRI-guided

Outcome measures

Primary outcome

Incidence of gastro-intestinal and/or urogenital toxicity, aiming for less than

5% grade >=3 toxicity will be determined by the Common Toxicity Criteria for

Adverse Events (CTCAE) version 4.0 (National Cancer Institute).

Secondary outcome

- To determine the technical feasibility of MRI guided focal high-dose rate

brachytherapy for localized prostate cancer

- Quality of life

- Biochemical disease free survival

Study description

Background summary

Favourable risk prostate cancer is common in men in developed countries. These cancers are often biologically indolent and therefore not clinically significant. However, no consensus has been reached with regard to the best approach of these tumours. Nowadays, low-dose-rate brachytherapy is often implemented for patients with favourable risk prostate cancer since it is a minimally invasive procedure. Still, severe toxicity remains a concern. Studies regarding high-dose-rate brachytherapy as monotherapeutic treatment of the entire prostate, show promising results regarding toxicity of bladder and rectum. Nevertheless grade 3 toxicity is still present. To reduce toxicity in patients with localized prostate cancer, focal treatment is warranted. This can be achieved with MRI guided high-dose-rate brachytherapy. In the past, focal treatment has not been explored since determination of exact tumour location was not precise. Our radiotherapy centre has a MRI high-dose-rate brachytherapy facility. With this facility, catheter placement can be done far more accurately, which makes focal treatment possible. By using focal treatment, less toxicity is expected. In earlier studies, a dose of 19 Gy to the entire

prostate was shown to be feasible. Therefore we believe that focal treatment of 19 Gy to the tumour focus will be of benefit to the patient with localized prostate cancer. In case of recurrent (biochemical) disease, retreatment will be applied.

Study objective

To assess toxicity of MRI guided high-dose-rate focal brachytherapy as monotherapy for favourable risk prostate cancer. As secondary objectives, technical feasibility, quality of life and biochemical free survival will be determined.

Study design

Prospective development study using MRI guidance to apply a single high dose rate brachytherapy as focal monotherapy for favourable risk prostate cancer. All UMC Utrecht prostate cancer patients meeting the inclusion criteria (see 4. Study population), will be considered for inclusion.
Before treatment, a diagnostic MRI with contrast will be made. During treatment, a MRI without contrast will be performed to visualize the brachytherapy catheters in relation to prostate anatomy. Six months after treatment, a diagnostic MRI will be done to assess treatment response.
The time span for inclusion of patients in this study will be three years. During the first 90 days, acute gastro-intestinal and/or genital-urinary toxicity will be monitored. Hereafter, late gastro-intestinal and/or genital-urinary toxicity will be assessed during a 10 year period. Toxicity will be determined by using the Common Toxicity Criteria for Adverse Events (CTCAE) version 4.0. Quality of life will also be measured during a 10 year period. The RAND-36, EORTC QLQ-PR-25, EORTC QLQ-C30 and IEFF-5 questionnaires will be used. For assessment of biochemical recurrence, Prostae Specific Antigen (PSA) monitoring will be performed during each follow-up visit. Follow-up consultations will be performed 4 weeks after treatment and thereafter every three months for the first year, every 6 months the second year and thereafter annually for up to ten years, according the Dutch prostate guideline (18).
In case of recurrent disease, a MRI and PET scan will be performed. Depending on MRI and PET findings, suitable re-treatment will be performed.

Intervention

High-dose-rate brachytherapy will be performed for patients with low to intermediate risk prostate carcinoma. The treatment will include a single fraction of 19 Gy. High-dose-rate brachytherapy will be performed by insertion of catheters under ultrasound guidance. Under MR guidance, cathether placement will be adjusted, according to the exact tumour position. Image datasets will be transferred into the treatment planning computer to create a simulation of

dose distribution to Gross Tumour Volume (GTV), prostate, urethra, rectum and bladder. Deliniation of the GTV will be performed by using the diagnostic MRI. The Clinical Target Volume (CTV) will be defined as GTV with wider margins, to account for tumour extension. The Planning Target Volume (PTV) will have no extra margins. The treatment will include one high-dose-rate treatment. After treatment, the implants will be removed and the patient will be discharged from the hospital

Study burden and risks

With stringent dose constraints to urethra, bladder and rectum, and state of the art planning procedure before focal high-dose-rate brachytherapy application, it is unlikely that this treatment modalitiy will induce severe toxicity. Above all, we expect that focal treatment will further reduce toxicity compared to current commonly used low-dose-rate brachytherapy. The additional MRI scan during treatment of focal high-dose-rate brachytherapy will induce no additional health risks. Focal high-dose-rate brachytherapy treatment of prostate cancer has never been implemented before. Therefore, recurrence rates of prostate cancer after this treatment modality are unknown. In case of a (biochemical) relapse, a MRI and PET scan will be performed and retreatment will be applied.

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 >= 65 years
- Patients with prostate cancer, T stage < T3, Gleason <=7, Prostate Specific Antigen (PSA) <10 ng/ml
- Tumour location technically feasible for brachytherapy
- Karnofski score >=70
- Written informed consent
- Fit for spinal anaesthesia

Exclusion criteria

- Previous pelvic radiotherapy for another malignancy
- Previous surgery or transurethral resection of the prostate
- Prostate cancer recurrence
- Patients who meet exclusion criteria for MRI following the protocol of the radiology department of the UMC Utrecht
- International Prostate Symptom Score (IPSS) >15
- Anticoagulant administration continuously required, except for platelet aggregation inhibitors (for example Ascal/Persantin)
- Discongruence between prostate biopsies and MR imaging

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-01-2013
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	24-10-2012
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	03-04-2013
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	30-10-2013
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	02-11-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	15-11-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	10-07-2019
Application type:	Amendment
Review commission:	METC NedMec

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	NL41443.041.12