Feasibility of MRI guided focal high-dose-rate brachytherapy for localized prostate cancer (Plaatselijke inwendige bestraling voor patiënten met prostaatkanker).

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21756

Source
NTR

Health condition

High-dose-rate brachytherapy
MRI-guided
Localized prostate cancer

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: University Medical Center Utrecht

Intervention

Outcome measures

Primary outcome

Incidence of gastro-intestinal and/or urogenital toxicity, aiming for less than 5% grade ≥3 toxicity.

Secondary outcome

1. To determine the technical feasibility of MRI guided focal high-dose rate brachytherapy for localized prostate cancer;
2. Quality of life;
3. 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 (LDR) brachytherapy is often implemented for patients with favourable risk prostate cancer, since it is a minimally invasive procedure. Still, grade 3 toxicity remains a concern in 5-34% of all series. Studies regarding high-dose-rate (HDR) brachytherapy (BT) as monotherapeutic treatment of the entire prostate, show promising results regarding toxicity of bladder and rectum. Nevertheless, severe 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. Currently, our radiotherapy centre is the only department worldwide with an MRI HDR brachytherapy facility, allowing MRI guided catheter placement and treatment. 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 adequate. 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, suitable re-treatment will be performed.

Country of recruitment: The Netherlands.

Study objective

To reduce treatment-related toxicity in patients with localized prostate cancer, focal treatment is warranted. This can be achieved with MRI guided high-dose-rate brachytherapy. We expect that a single dose of 19 Gy to the tumour volume will be of benefit to the patient with localized prostate cancer.

Study design

The treatment includes one high-dose-rate brachytherapy procedure, administering 19 Gy in a single session.
Questionnaires will be used to assess toxicity and quality of life (before treatment, one month

after treatment, every 3 months the first year, every 6 months the second year, thereafter once a year for up to 10 years). For assessment of biochemical recurrence, PSA monitoring will be performed during each visit.

Follow-up time points:
4 weeks, 3 months, 6 months, 9 months, 12 months, 18 months, 24 months, 36 months, 48 months, 60 months, 72 months, 84 months, 96 months, 108 months, 120 months.

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.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age ≥65 years;
2. Patients with prostate cancer, T stage ≤T2c, Gleason ≤7, Prostate Specific Antigen (PSA) <10 ng/ml;
3. Tumour location technically feasible for brachytherapy;
4. Karnofski score ≥70;
5. Written informed consent;

6. Fit for spinal anaesthesia.

Exclusion criteria

1. Previous pelvic radiotherapy for another malignancy;
2. Previous surgery or transurethral resection of the prostate;
3. Prostate cancer recurrence;
4. Patients who meet exclusion criteria for MRI following the protocol of the radiology department of the UMC Utrecht;
5. International Prostate Symptom Score (IPSS) >15;
6. Anticoagulant administration continuously required;
7. Discongruence between prostate biopsies and MR imaging.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-01-2013
Enrollment:	30
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	11-01-2013
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	NL3624
NTR-old	NTR3790
Other	METC UMCU : METC 12-402
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A