Eenmalige plaatselijke inwendige bestraling voor de behandeling van patiënten met teruggekeerde prostaatkanker

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20394

Source
NTR

Brief title
PRECISE

Health condition

Prostate cancer
High-dose-rate brachytherapy
Recurrent disease

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

To investigate the occurrence of acute and late (>3 months) grade >2 GI and/or GU toxicity (aiming for <10% grade >2 toxicity) after MRI-guided focal salvage HDR-BT for locally recurrent prostate cancer.

Secondary outcome

- QoL;
- Biochemical disease free survival;
- Assessment of dose restrictions to prevent/reduce acute and late GU/GI toxicity;
- Predictive factors for tumor control, to optimize patient selection.

Study description

Background summary

Despite improvements in primary curative treatment modalities, prostate cancer recurrences are common. Various salvage treatments, such as radical prostatectomy, low-dose-rate brachytherapy, external beam radiotherapy, high intensity focused ultrasound and cryosurgery have been investigated. However, because of high failure and toxicity rates, these treatment modalities remain unpopular. High failure rates can be reduced by excluding patients with high risk characteristics for early distant metastases, for whom local salvage treatment has no benefit. High toxicity rates in whole-gland salvage irradiation therapies are caused by accumulation of dose to surrounding organs at risk. To reduce toxicity, focal therapy is warranted. With advancements in imaging modalities, determination of the exact tumor location has become possible, in addition to adequate exclusion of metastatic disease. Currently, the radiotherapy department in the University Medical Centre Utrecht has a 1.5T magnetic resonance imaging (MRI) high-dose-rate brachytherapy (HDR-BT) facility, allowing for optimal visualization during treatment. With this facility, focal treatment is possible by inserting catheters into the tumor under MRI-guidance. Due to the steep dose fall-off in brachytherapy, low radiation doses will be expected in the surrounding healthy tissues, while maximum dose can be applied to the tumor. Therefore, less toxicity to the organs at risk is expected, while tumor control is maintained. In earlier studies, it was shown that salvage HDR-BT is feasible. Moreover, results regarding toxicity are promising. Therefore, we expect that focal salvage MRI-guided HDR-BT will be of benefit in patients with locally recurrent prostate cancer.

Study objective

The purpose of this study is to evaluate toxicity and oncologic outcomes of MRI-guided focal salvage high-dose-rate brachytherapy (HDR-BT). In earlier studies, it was shown that focal salvage HDR-BT is feasible and results regarding toxicity are promising. Therefore, it is expected that focal salvage HDR-BT will be of benefit in patients with locally recurrent prostate cancer, with respect to both toxicity and tumor control.

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

Single fraction focal high-dose-rate brachytherapy to a dose of 19 Gray

Contacts

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Eligibility criteria

Inclusion criteria

- Age >18 years;
- Recurrence >2 years after primary radiotherapy treatment (LDR-BT or EBRT);
- PSA at time of salvage <20 ng/ml;
- PSA doubling time >9 months;
- Maximum stage T3b tumor (extra prostatic extension into the seminal vesicle(s));

- Acceptable toxicity of primary radiation treatment (IPSS <15);
- Concordance between PSMA-PET/CT and mp-MRI;
- Tumor location technically feasible for brachytherapy;
- Karnofsky score >70
- Written informed consent;
- Fit for spinal anesthesia.

Exclusion criteria

- Distant metastases;
- Previous pelvic radiotherapy for another malignancy;
- Prior prostate treatment(s) like a recent transurethral resection of the prostate (TURP) (<6 months before focal salvage HDR treatment), HIFU or cryosurgery, except for radiotherapy;
- Contraindications for MRI;
- Severe toxicity from primary radiation treatment (IPSS >15);
- Anticoagulant administration continuously required, except for platelet aggregation inhibitors (for example Ascal/Persantin).

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:	Recruiting
Start date (anticipated):	01-02-2018
Enrollment:	88
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	05-02-2018
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	NL6827
NTR-old	NTR7014
Other	METC UMC Utrecht : METC 17-790

Study results

Summary results
None