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

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20394

Bron
Nationaal Trial Register

Verkorte titel
PRECISE

Aandoening

Prostate cancer
High-dose-rate brachytherapy
Recurrent disease

Ondersteuning

Primaire sponsor: University Medical Center Utrecht
Overige ondersteuning: KWF (Dutch Cancer Society)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2018
Aantal proefpersonen:	88
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	05-02-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6827
NTR-old	NTR7014
Ander register	METC UMC Utrecht : METC 17-790

Resultaten

Samenvatting resultaten
None