Feasibility of MRI-guided focal salvage high-dose-rate brachytherapy for locally recurrent prostate cancer

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

Samenvatting

ID

NL-OMON27850

Bron
NTR

Aandoening

Prostate cancer, high-dose-rate (HDR) brachytherapy, radiorecurrent disease.

Ondersteuning

Primaire sponsor: University Medical Center Utrecht
Overige ondersteuning: University Medical Center Utrecht

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To investigate the occurrence of gastrointestinal and/or genitourinary toxicity after focal salvage HDR-BT for locally recurrent prostate cancer.

Toelichting onderzoek

Achtergrond van het onderzoek

Prostate cancer recurrences after primary treatment are common, despite improvements in primary curative treatment modalities. Various salvage treatment modalities, such as radical prostatectomy, low-dose-rate brachytherapy, external beam radiotherapy, HIFU (high intensity focused ultrasound) and cryosurgery have been investigated. However, because of high failure and high toxicity rates, these treatment modalities remain unpopular. High failure rates can be reduced by excluding patients with a high risk for early distant metastases. In these patients, local salvage treatment will not be of any benefit. High toxicity rates can be explained by the fact that salvage therapy is often aimed at the entire prostate. With radiation treatment, this causes an accumulation of irradiation dose to normal tissues. To reduce the burden of radiation treatment, focal therapy is warranted. This can be achieved with MRI-guided focal salvage HDR-BT (high-dose-rate brachytherapy). In the past, focal salvage treatment was not feasible, because determination of the exact tumour location was not precise. Currently, our radiotherapy centre has an MRI HDR-BT facility, allowing MRI-guided catheter placement and treatment. Under MRI-guidance, catheter placement can be done far more accurately, which makes focal treatment possible. Due to the steep dose fall-off in brachytherapy, low radiation doses are expected in the surrounding healthy tissues. Therefore, patients will experience less toxicity of the organs at risk. In earlier studies, results regarding toxicity are promising. Therefore, we expect that MRI-guided salvage treatment by using HDR-BT will be of benefit in patients with recurrent prostate cancer.

Doel van het onderzoek

The purpose of this study is to evaluate toxicity and feasibility of MRI-guided focal salvage high-dose-rate brachytherapy (HDR-BT) in patients with locally recurrent prostate cancer. In comparison with whole-gland salvage techniques, focal treatment is expected to reduce toxicity, while maintaining cancer 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 HDR treatment to a dose of 19 Gray

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age >18 years;
- Biopsy proven local recurrence;
- Biopsy proven recurrence at least 2 years after primary radiotherapy treatment (low-dose-rate brachytherapy or external beam radiation therapy);
- Limited and non-aggressive tumor presentation at time of salvage (PSA at time of salvage <10);
- PSA doubling time more than 12 months;
- Acceptable toxicity of primary radiation treatment (IPSS<15);
- Tumour location technically feasible for brachytherapy;
- Tumour on MRI and PSMA/choline PET scan within anatomical prostate borders (no extracapsular growth or metastases);
- Karnofsky score >70;
- Written informed consent;
- Fit for anaesthesia.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Distant metastases;
- Severe toxicity from primary radiation treatment (IPSS>15);
- Patients who meet exclusion criteria for MRI following the protocol of the radiology department of the UMC Utrecht (see appendix);
- Anticoagulant administration continuously required, except for Ascal;
- Discongruence between prostate biopsies and contrast MR imaging;
- Prior prostate treatment(s) (like a recent TURP (<6 months before focal salvage HDR treatment), HIFU, cryosurgery), except for radiotherapy.

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 gestopt
(Verwachte) startdatum:	01-05-2013
Aantal proefpersonen:	30
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	17-10-2016

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	NL5942
NTR-old	NTR6123
Ander register	METC UMCU : METC 12-622

Resultaten

Samenvatting resultaten
None