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

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

## Samenvatting

### ID

NL-OMON21756

**Bron**
NTR

**Aandoening**

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

### Ondersteuning

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

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

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

# Toelichting onderzoek

### Achtergrond van het onderzoek

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.

### Doel van het onderzoek

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.

### 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**

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.

# Contactpersonen

## Publiek

UMC Utrecht, Department of Radiotherapy
J.R.N. van der Voort van Zyp
Utrecht 3508 GA
The Netherlands
+31 (0)88 7558800

## Wetenschappelijk

UMC Utrecht, Department of Radiotherapy
J.R.N. van der Voort van Zyp
Utrecht 3508 GA
The Netherlands
+31 (0)88 7558800

# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

## 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: | 21-01-2013 |
| 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: | 11-01-2013 |
| 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 | NL3624 |
| NTR-old | NTR3790 |
| Ander register | METC UMCU : METC 12-402 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Resultaten

**Samenvatting resultaten**
N/A