PRostatE Cancer MRI guided focal SalvagE high-dose-rate brachytherapy

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To assess toxicity of MRI-guided focal salvage high-dose-rate brachytherapy (HDR-BT) in patients with locally recurrent prostate cancer. Secondary objectives are quality of life, biochemical disease free survival, dose restrictions, technical...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Reproductive neoplasms male malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON48560

Source
ToetsingOnline

Brief title
PRECISE

Condition

- Reproductive neoplasms male malignant and unspecified
- Prostatic disorders (excl infections and inflammations)
- Male genital tract therapeutic procedures

Synonym
prostate cancer, Recurrent prostate carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: KWF Kankerbestrijding

Intervention

Keyword: Focal therapy, High-dose-rate brachytherapy, MRI-guided, Recurrent prostate cancer

Outcome measures

Primary outcome

The incidence of gastrointestinal and/or genitourinary toxicity, which will be

determined by the Common Terminology Criteria for Adverse Events (CTCAE)

version 4.0.

Secondary outcome

- QoL assessment by questionnaires (RAND-36, EORTC QLQ-PR-25, EORTC QLQ-C30,

IPSS, IIEF-5);

- PSA-monitoring for evaluation of biochemical disease free survival;

- Dose restrictions analysis by relating dosage to toxicity to prevent/reduce

toxicity;

- Evaluation of catheter shifts during focal salvage HDR-BT;

- Prediction-modeling for the determination of predictive factors for tumor

control, to further 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. At the Haaglanden Medical Center in the Hague, an operating theatre is available for a similar brachytherapy implant procedure. With these facilities, 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

To assess toxicity of MRI-guided focal salvage high-dose-rate brachytherapy (HDR-BT) in patients with locally recurrent prostate cancer. Secondary objectives are quality of life, biochemical disease free survival, dose restrictions, technical aspects (catheter shifts) and predictive factors for tumor control.

Study design

Multicenter prospective phase II single-arm study.

Intervention

MRI-guided focal salvage HDR-BT in a single fraction of 19 Gray (Gy).

Study burden and risks

In order to keep toxicity to a minimum, strict dose constraints to the organs at risk (urethra, bladder and rectum) will be applied using state of the art planning procedures prior to focal salvage HDR-BT. If the dose to the organs at risk is exceeded, the dose to the planning target volume (PTV) will be decreased. Within our UMCU feasibility study on focal salvage HDR-BT (METC number 12-622), so far toxicity has been limited to one patient experiencing grade 3 genitourinary toxicity (<5%). Furthermore, hormonal treatment may be prevented or delayed in the future, thereby preventing hormone induced toxicity. Moreover, the postponement of castration resistance can potentially

increase survival. To investigate quality of life, validated questionnaires will be used. The use of MRI scans will induce no additional health risks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age >=18 years;
- Recurrence >=2 years after primary radiotherapy treatment (low-dose-rate brachytherapy of external beam radiation therapy);
- Prostate Specific Antigen (PSA) at time of salvage <=20 ng/ml;
- Prostate Specific Antigen (PSA) doubling time >=9 months;
- Stage <=T3b tumor (extra prostatic extension into the seminal vesicle(s));
- Acceptable toxicity of primary radiation treatment (International Prostate Symptom Score (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 phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-02-2018
Enrollment:	88
Type:	Actual

Ethics review

Approved WMO Date:	22-01-2018
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	25-10-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	26-08-2021
Application type:	Amendment
Review commission:	METC NedMec

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
CCMO	NL63728.041.17
Other	NL6827