RObotic mri-guided high dose rate Brachytherapy Needle implantation in the proState - a proof of concept study

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To investigate the technical feasibility of inserting a brachytherapy needle into the prostate to a defined tumour target point using a robotic device.

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

Summary

ID

NL-OMON55715

Source
ToetsingOnline

Brief title
ROBiNSon

Condition

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

Synonym
Prostate cancer, prostatic carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Brachytherapy, MRI-guided radiotherapy, Prostate cancer, Robotic

Outcome measures

Primary outcome

The primary endpoint is the technical feasibility of using the robotic needle-implant device, which will be determined by the needle-to-tumour-target distance.

Secondary outcome

- To determine the geometric accuracy of the brachytherapy needle position in the prostate compared to the planned position (quantified by needle-to-geometric-target (NTG) distance;

- To quantify the deformation of the prostate during and after needle insertion;

- To determine the duration of a robotic needle insertion procedure;

- To assess toxicity related to treatment.

Study description

Background summary

Focal treatment of localized recurrent prostate cancer after primary radiotherapy has the potential to maintain cancer control, while decreasing treatment-related toxicity that is associated with whole-gland salvage treatments. A promising focal salvage technique is magnetic resonance imaging (MRI)-guided high-dose-rate brachytherapy (HDR-BT). The department of Radiotherapy at the University Medical Centre Utrecht (UMCU) is equipped with an MRI HDR-BT facility: a shielded room with a 1.5T MRI scanner, where brachytherapy needle implantation and dose delivery take place under MRI guidance.
Within the current HDR-BT treatment, the prostate is directly visualised using trans-rectal ultrasound (TRUS), whereas the target tumour volume is visualised indirectly through delineations from a pre-radiation MRI scan which are fused

with the TRUS images. Using this visual guidance, brachytherapy needles are manually inserted into the tumour for targeted radiation of the tumour volume, by temporarily loading them with a radioactive source. A dose of 19 Gray (Gy) is delivered from an iridium (Ir)-192 source.
A shortcoming in the current workflow is the indirect visualization of the tumour volume: it requires registration of pre-operative MRI images to live intra-operative TRUS images. This registration becomes less accurate during needle implantation as the firm prostate tissue is displaced and deformed due to oedema. Additionally, manual implantation can be time-consuming and lead to more trauma as the (pre-irradiated) prostate can be difficult to manipulate and needles often need to be repositioned repeatedly in order to ensure optimal placement. However, since space is limited within the MRI bore itself, manual brachytherapy needle insertion under real-time MRI guidance is physically not possible.
To overcome these shortcomings, a robotic MRI-compatible implantation device was developed at our institution to perform focal salvage HDR-BT under MRI-guidance. The robot fits in a 1.5T MRI scanner and can be placed between the patient*s legs. A first feasibility study showed that it was feasible to use this robotic device for implantation of gold fiducial markers into the prostate (protocol number NL21143.041.08). However, it was found that the implantation momentum was not sufficient to avoid prostate deformation. Hereafter the robot was optimized and redesigned to allow HDR-BT treatment of the prostate with angulated needle trajectories. The accuracy of the needle angulations was tested in air and in an agar phantom, with promising results regarding needle alignment. We anticipate that the tested image-based workflow is also feasible for in vivo validation of the robotic device.
To investigate the in vivo feasibility, part of the HDR-BT procedure will be performed using the MRI-compatible robotic needle implantation device. Prior to the standard manual implantation procedure, a single needle will be introduced into the prostate by the robot and a radiation dose will be delivered.
In the future, an implantation procedure performed entirely by the robotic device can allow for a reduction in the number of brachytherapy needles needed due to optimization of radiation tumour coverage. This potentially leads to lower toxicity rates: there will be less manipulation of the prostate and healthy organs at risk (OAR) are spared due to optimal dose distribution. Furthermore, we expect a reduction in the total procedure duration. Additionally, we anticipate better tracking of the tumour volume during complete MRI-guided implantation, thereby achieving increased tumour control.

Study objective

To investigate the technical feasibility of inserting a brachytherapy needle into the prostate to a defined tumour target point using a robotic device.

Study design

Single-centre single-arm prospective development study.

Intervention

Single-needle insertion into the prostate by an MR-compatible robotic device, prior to the conventional manual focal salvage HDR-BT procedure.

Study burden and risks

Within the conventional focal salvage HDR-BT procedure, the risk of toxicity is minimized by applying strict dose constraints for the OAR (urethra, bladder and rectum). State of the art planning procedures are used for dose calculations. In the current study, the same planning procedure will be used.
Needle insertion by the robotic device will be MRI-guided. Deviation of the needle position will be detected immediately and can be corrected for in the dose calculation. Taking into account that only part of the dose will be delivered through the robotically placed needle and the stringent MRI-monitoring, we expect this treatment to be safe for the patient. No additional anaesthesia will be required, since patients already receive spinal anaesthesia for the conventional HDR-BT procedure. Approximately 2.5 hours will be needed for preparation and execution of the robotic needle insertion procedure, in addition to the 2-3 hours needed for the manual procedure.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- All eligibility criteria for focal salvage high-dose-rate brachytherapy (HDR-BT) as currently followed by the department of Radiotherapy at the UMCU:
o Age >=18 years;
o Local recurrence >2 years after primary treatment.
o Stage <=T3b tumour;
o Recurrent lesion visible on 68Ga-PSMA-PET-CT and at least 1 sequence of the mp-MRI (T2 weighted (T2 weighted (T2W), DCE or DWI);
o Karnofsky score >=70.
- Prior prostate cancer treatment with standard external beam radiation therapy (EBRT), for which fiducial gold markers were placed in the prostate;
- Tumour location technically feasible for robotic needle placement as determined on diagnostic MRI scan and PET-CT scan;
- Written informed consent.

Exclusion criteria

- Any contra-indications for focal salvage HDR-BT as currently followed by the department of Radiotherapy at the UMCU:
o Metastatic disease;
o Other prostate cancer treatments in the past (HIFU or cryosurgery), except for radiotherapy;
o Trans-urethral resection of the prostate (TURP) within the past 6 months;
o Prior radiotherapy for a malignancy in the pelvic area, other than prostate cancer;
o Continuously required anticoagulant administration, except for platelet aggregation inhibitors (for example Ascal/Persantin).
- Hypofractionated EBRT as primary prostate cancer treatment;
- Less than 3 gold markers visible in the prostate on the pre-treatment MRI-scan;
- Physical inability to spread the legs sufficiently for positioning in the leg supports;

- Contra-indications for MRI.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-09-2019
Enrollment:	5
Type:	Actual

Medical products/devices used

Generic name:	Robot Single Needle for HDR
Registration:	No

Ethics review

Approved WMO Date:	13-12-2018
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	08-02-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	31-12-2021

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	NL67255.041.18