Partial or whole gland brachytherapy to maintain erections

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26328

Source
Nationaal Trial Register

Brief title
POWER

Health condition

Erectile dysfunction (erectiele disfunctie), Focal prostate brachytherapy (Focale prostaat brachytherapie), Late radiation effects (Late bestralingseffecten), Quality of life (Kwaliteit van leven). Oncologic efficacy (Oncologische effectiviteit)

Sponsors and support

Primary sponsor: Amsterdam Universitair Medisch Centrum, location Academic Medical Center
Source(s) of monetary or material Support: Dutch Cancer Society (KWF)
Elekta
Deutschen Gesellschaft für Urologie (DGU)

Intervention

Outcome measures

Primary outcome

Deterioration of erectile function by assessment of the IIEF-5 score. A drop of at least 5 points compared to baseline value or a need to start with a phosphodiesterase 5 inhibitor (PDE5 inhibitor) (or other medical interventions to improve erections) at last follow- up is considered as an event.

Secondary outcome

The incidence of late gastro-intestinal (GI) and genito-urinary (GU) toxicity (CTCAEv4 and IPSS)

quality of life after treatment completion (EORTC QLQ-C30 and PR25)

Progression of local disease histologically and radiological.

Study description

Background summary

Rationale: A drawback of the standard whole gland brachytherapy for prostate cancer is that large volumes of sensitive organs and structures are irradiated to a high dose. The unavoidable dose on these organs and structures will lead to unwanted late effects. Reducing the irradiated volume for a selected group of patients with unilateral low-risk significant disease can reduce the probability of late effects. The hypothesis in this study is that by performing hemigland brachytherapy the incidence of erectile dysfunction can be reduced by 20%.

Objective: The main objective is to assess if partial prostate brachytherapy will lead to less erectile dysfunction than whole gland prostate brachytherapy.

Secondary objectives are:

- To assess differences in urinary and rectal late effects between whole gland and partial prostate brachytherapy.

- To assess differences in post-procedural quality of life measured by EORTC QLQ- C30 and QLQ-PR25 questionnaire.

- To assess the local oncological efficacy as measured by the proportion of men who are free

of local prostate cancer in the two different groups. This will be examined by standardized 12 core prostate biopsies and mpMRI.

Study design: This study is designed as a randomized study between whole gland prostate brachytherapy (control arm) and hemigland prostate brachytherapy (experimental arm). Study population: The study population consists of patients with proven unilateral significant adenocarcinoma of the prostate. The tumour is unilateral localised by histopathology and mpMRI. The accepted clinical stages are T1c-T2b with (Gleason 3 + 3 with ≥30% tumor of all taken cores and PSA ≤ 20 ng/ml) or (Gleason 3+4 or Gleason 4 + 3 and PSA ≤ 15 ng/ml). Eligible patients are sexually active. Intervention (if applicable): All patients are treated with brachytherapy either on the whole gland or hemigland. The treatments are performed with a permanent implantation with I-125 sources or a temporary implantation with HDR.

Main study parameters/endpoints: The primary endpoint is deterioration of erectile function by assessment of the IIEF-5 score. A drop of at least 5 points compared to baseline value or a need to start with a phosphodiesterase 5 inhibitor (PDE5 inhibitor) (or other medical interventions to improve erections) at last follow-up is considered as an event. Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The treatment burden will not be much different than what is common for the standard whole gland brachytherapy. After the regular diagnostics patients will be treated either on a same admission-day policy or a short hospitalisation. That will not be different between the two study arms. To be eligible for this study extra investigations will be performed, such as template prostate biopsies and mpMRI, which is not standard practice everywhere. In the follow-up, late effect and quality of life forms need to be filled in by the patients and standard 12 core prostate biopsies and mpMRI will be performed.

When only a part of the prostate is treated there is evidently a risk to undertreat and jeopardize the patient’s life. For this reason a non-inferiority analysis will be conducted to test the safety of partial treatment.

Study objective

Hemigland prostate brachytherapy will reduce the absolute incidence of erectile dysfunction by 20% compared to whole gland prostate brachytherapy

Study design

Accrual time 3 years.

Minimal follow-up time 5 years.

Intervention

Prostate brachytherapy either I125 (144 Gy) or HDR (2 x 13.5 Gy).

Control arm: Whole gland brachytherapy

Experimental arm: Hemigland brachytherapy

Contacts

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Eligibility criteria

Inclusion criteria

1. Histologically adenocarcinoma confirmed on systematic biopsies and targeted biopsies after mpMRI. Optional is to perform template prostate biopsies (18-26 cores) with targeted biopsies after mpMRI

2. Unilateral significant tumor confirmed by histology (see point 4).

3. Clinical stage T1c-T2b (Appendix B)

4. Gleason score 3 + 3 with ≥30% tumor of all taken cores (ISUP Grade Group 1), Gleason score 3 + 4 (ISUP Grade Group 2), and Gleason 4 + 3 (ISUP Grade Group 3)

5. PSA ≤15 ng/ml and Gleason 7 (Grade Group 2-3) or PSA ≤20 ng/mL and Gleason 6 (Grade Group 1)

6. Baseline IIEF-5 score ≥12 (Appendix C)

7. Sexually active

8. International Prostate Symptom Score (IPSS) ≤ 20 (Appendix D)

9. WHO performance score ≤ 2 (Appendix E)

10. Age > 18 years
11. Written informed consent

Exclusion criteria

1. Contraindication for mpMRI

2. Bleeding disorder preventing invasive treatment as a prostate implantation

3. Not able to stop coumarine derivates

4. Active urinary tract infection

5. Any history of bladder neck stricture

6. Comorbidity preventing general or spinal anesthesia

7. Any history of inflammatory bowel disease

8. Prior or concurrent malignancy except for non-melanoma skin cancer or other malignancy from which the patient has been cured for at least 5 years

9. Life expectancy of < 5 years

10. Prostate calcifications greater than 5 mm

11. Chemotherapy for prostate cancer

12. Hormonal therapy for prostate cancer within 1 year prior to procedure

13. Previous radiation to pelvis

14. Recurrent prostate cancer

15. Transurethral resection of the prostate or urethral stent

16. Prior major rectal surgery (except haemorrhoids)

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2018
Enrollment:	254
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	13-06-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55755
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7073
NTR-old	NTR7271
CCMO	NL62771.018.17
OMON	NL-OMON55755

Study results