Randomized trial for the evaluation of erectile dysfunction after whole or partial gland prostate brachytherapy: POWER (Partial or Whole gland for Erections)

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

Summary

ID

NL-OMON55755

Source
ToetsingOnline

Brief title
POWER

Condition

- Reproductive neoplasms male malignant and unspecified

Synonym
prostate cancer, prostate carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Elekta,KWF Kankerbestrijding;Deutschen Gesellschaft fur Urologie;Elekta

Intervention

Keyword: brachytherapy, erectile dysfunction, focal therapy, prostate

Outcome measures

Primary outcome

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.

Secondary outcome

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 QLQC30 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 description

Background summary

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%.

Study 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 QLQC30 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).

Intervention

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.

Study burden and risks

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.

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

1. Histologically adenocarcinoma on systematic prostate biopsies and targeted biopsies after mpMRI
2. Unilateral tumor confirmed by histology.
3. Clinical stage T1c-T2b
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
7. Sexually active
8. International Prostate Symptom Score (IPSS) <= 20
9. WHO performance score <= 2
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:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-07-2019
Enrollment:	65
Type:	Actual

Ethics review

Approved WMO Date:	24-05-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-08-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-10-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-10-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-04-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26328
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL62771.018.17
Other	NL7073/ NTR7271
OMON	NL-OMON26328