Prospective multi-centre study of low-dose Iodine125 (I-125) prostate brachytherapy performed after transurethral resection. PROBATE study

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To test in a prospective study the feasibility and outcome of low dose rate I-125 seed brachytherapy to treat early low risk prostate cancer in patients who have had previous TURP using specific recommendations on target and organs at risk dose...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive and genitourinary neoplasms gender unspecified NEC
Study type	Interventional

Summary

ID

NL-OMON37110

Source
ToetsingOnline

Brief title
I125 postTURP

Condition

- Reproductive and genitourinary neoplasms gender unspecified NEC

Synonym
Prostate cancer, prostate malignancy

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: I125, Prostatic neoplasms, Toxicity, TURP

Outcome measures

Primary outcome

Acute and late urinary toxicity defined by IPSS and CTCAEv4

Secondary outcome

- Gastro-intestinal and sexual function

- Biochemical disease free survival (Phoenix-definition).

- Incidence of seed loss at 1month and 6 months after implant

Study description

Background summary

Low dose rate I-125 seed brachytherapy is an established treatment for localised low risk prostate cancer. Both the ABS recommendations on permanent seed implant and the GEC-ESTRO guidelines consider prior TURp (Transurethral Resection of the prostate) a (relative) contra-indication for prostate permanent seed brachytherapy. In a lot of, even experienced, brachytherapy centres, the history of endoscopic resection of the prostate soon became an absolute contra-indication for prostate brachytherapy. The small number of publications on this item confirms this hypothesis. These recommendations were principally based on an early report from the Seattle group, describing their initial experience and reporting a major risk of significant toxicity, primarily urinary incontinence, in brachytherapy patients who had undergone prior TURp. However, much of this data originated from patients treated with early dosimetry planning systems and homogeneous loading of the radioactive isotopes when imaging and dosimetry was not well developed and the experience didn*t assess large patient samples.
With more extensive experience in the field of prostate brachytherapy, the optimization of imaging techniques and improved loading and dosimetry techniques, there is little doubt that the complication rate in this group of patients has also considerably decreased. More recent reports dealing with this specific item suggest that brachytherapy can be safely performed in a TURp

patient group on condition that modern imaging and optimized dosimetry techniques are used. Unfortunately, experience remains limited; reports are few and deal with small patient groups.

Study objective

To test in a prospective study the feasibility and outcome of low dose rate I-125 seed brachytherapy to treat early low risk prostate cancer in patients who have had previous TURP using specific recommendations on target and organs at risk dose parameters.

Study design

This study is designed as a prospective phase II study. Stopping rules are defined to stop the study if toxicity exceed what is expected.

Intervention

Brachytherapy with I-125 sources

Study burden and risks

I-125 implants are performed with a 1-day hospitalization. This procedure has proven to be very efficacious with a survival rate over 90% for low-risk prostate cancer. In contrast, external beam radiotherapy can last 7 weeks. Complaints that can follow an implant are due to obstructive and iritative changes. Because of the experimental design of the study there is a possibility of increased toxicity.

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

-Histologically proven prostate cancer (adenocarcinoma) of low or intermediate risk following the D*Amico classification.
-Prostate volume < 50 cc
-History of TransUrethral Resection of the prostate (TURp), performed at least 3 months before the brachytherapy procedure.
-Rim of prostate tissue of at least 1 cm around the post-TURp urethral defect at thepostero-lateral sides of the prostate
-Absence of significant TURP-induced urinary incontinence
- IPSS <15

Exclusion criteria

-Locally advanced (stage T3 or T4 , or metastatic (stage N+ or M+) prostate cancer
-High grade tumours defined by Gleason score 8 or above
-Co-morbidity which would exclude the patient from a transperineal implant procedure.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-08-2013
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	12-11-2012
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
Other	LTHT R & D: CO11/9837
CCMO	NL40917.018.12