Influence of pre- and post-operative pelvic floor muscle exercises (PFME) on urinary incontinence after retropubic radical prostatectomy and robotic radical prostatectomy.

No registrations found.

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

Summary

ID

NL-OMON28730

Source
NTR

Brief title
N/A

Health condition

Prostate cancer, urinary incontinence, pelvic floor muscle exercises

Sponsors and support

Primary sponsor: Katholieke Universiteit Leuven, Faculteit Bewegings- en Revalidatiewetenschappen
Source(s) of monetary or material Support: Institute for the Promotion of Innovation by Science and Technology in Flanders (IWT), Toegepast Biomedischa onderzoek met een primaire Maatschappelijk finaliteit (TBM)

Intervention

Outcome measures

Primary outcome

Duration and degree of urinary incontinence: All patients from the control group and from the experimental group are measured first preoperatively and then 1 month, 3 months, 6 months and 1 year after catheter withdrawal.

Secondary outcome

1. At each measurement session pelvic muscle tone, strength, endurance and exhaustion are evaluated;

2. Physical activity: pre-operatively, 1 month, 3 months, 6 months and 1 year after catheter withdrawal the patient fills in the 'physical activity and sports participation' questionnaire;

3. Erectile dysfunction: pre-operatively, 1 month, 3 months, 6 months and 1 year after catheter withdrawal the patient fills in the International Prostate Symptom Score (IPSS).

Study description

Background summary

Prostate cancer is the most common cancer in men on this moment. Radical prostatectomy for localized prostate cancer was always done via retropubic (open) approach. However robotic prostatectomy becomes more and more the treatment of choice. Urinary incontinence and erectile dysfunction are the most embarrassing complications after prostatectomy. Pelvic floor muscle exercises can reduce incontinence and improve erectile function. The purpose of this study is to compare the complications of both surgeries and to evaluate the influence of pelvic floor muscle exercises given before catheter withdrawal.

Study objective

1. Patients, starting with PFME before radical prostatectomy, have a shorter duration and a lower degree of post-operative urinary incontinence than patients who start with PFME after surgery;

2. Patients, performing pre-operative PFME and PFME during catheter wearing, who develop urinary incontinence, will have a smaller amount of urine loss and urinary incontinence will be reduced more easily compared with patients receiving only exercises after catheter withdrawal;

3. Patients, who had a robotic radical prostatectomy, will restart sooner their pre-operative

physical activity level than patients who had a retropubic radical prostatectomy;

4. Patients, who had a robotic radical prostatectomy, will regain urinary incontinence sooner than patients who had a retropubic radical prostatectomy.

Study design

1. After 12 months, approximately 120 patients are measured preoperatively and have started their physiotherapeutic treatment;

2. After 18 months, all patients are included in the study and started their physiotherapeutic treatment;

3. After 30 months all patients are being followed until one year after surgery. Data can be processed.

Intervention

Before surgery (retropubic or robotic) the patient will be randomly assigned to the experimental group, starting PFME before surgery or to the control group, starting PFME after catheter withdrawal.

The pelvic floor muscle training program consists of exercises of the pelvic floor manually controlled by the therapist and supplied with EMG biofeedback and electrostimulation in case of a weak pelvic floor. Every patient receives individual treatment on an outpatient basis once a week. Further the patient performs an exercise scheme independently at home.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients who will have a retropubic radical prostatectomy or a robotic radical prostatectomy for localised or locally advanced prostate cancer in the University Hospital Gasthuisberg in Leuven;

2. Patients who can participate in pelvic floor muscle training during the entire study period.

Exclusion criteria

1. Patients who refuse to participate in the study;

2. Patients who are not able to perform PFME because of cognitive problems.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2009
Enrollment:	180
Type:	Anticipated

Ethics review

Positive opinion

Date:	12-08-2009
Application type:	First submission

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
NTR-new	NL1841
NTR-old	NTR1953
Other	IWT : 080678
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A