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

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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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28730

Bron
NTR

Verkorte titel
N/A

Aandoening

Prostate cancer, urinary incontinence, pelvic floor muscle exercises

Ondersteuning

Primaire sponsor: Katholieke Universiteit Leuven, Faculteit Bewegings- en Revalidatiewetenschappen
Overige ondersteuning: Institute for the Promotion of Innovation by Science and Technology in Flanders (IWT), Toegepast Biomedischa onderzoek met een primaire Maatschappelijk finaliteit (TBM)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients who refuse to participate in the study;

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2009
Aantal proefpersonen:	180
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	12-08-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1841
NTR-old	NTR1953
Ander register	IWT : 080678
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A