The influence of pelvic floor muscle training during 3 months in men, who still suffer from erectile dysfunction 12 months after open or robot radical prostatectomy: A randomised controlled trial.

No registrations found.

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

Summary

ID

NL-OMON29363

Source
Nationaal Trial Register

Health condition

prostate cancer, erectile dysfunction, open radical prostatectomy, robot radical prostatectomy, pelvic floor muscle exercises

Sponsors and support

Primary sponsor: Katholieke Universiteit Leuven,
Faculteit Bewegings- en Revalidatiewetenschappen
Source(s) of monetary or material Support: Katholieke Universiteit Leuven,
Faculteit Bewegings- en Revalidatiewetenschappen

Intervention

Outcome measures

Primary outcome

Improvement in erectile function: The patients will be evaluated by filling in the 'International Index of Erectile Function- Questionnaire' and the 'Erectile Hardness Scale' at several time points.

Secondary outcome

At the same time points the patient and his partner will be interviewed concerning the quality of the erection, orgasm and relation.

Study description

Background summary

Prostate cancer is the most common cancer in men on this moment. Radical prostatectomy for localized prostate cancer is done via a retropubic (open) or robot radical prostatectomy. Urinary incontinence and erectile dysfunction are the most embarrassing complications after prostatectomy. Twelve months after surgery, many patients still suffer from erectile dysfunction. Pelvic floor muscle exercises can improve erectile function. The purpose of this study is to evaluate the influence of a therapy program (pelvic floor muscle training) during 3 months for erectile dysfunction, 12 months after a radical prostatectomy. Further we also want to compare the recovery of erectile function after both surgical approaches.

Study objective

1. Patients, who still suffer from erectile dysfunction, 12 months after a radical prostatectomy, can improve their erectile function by performing an intensive therapy program for their pelvic floor muscles;

2. Patients after robot surgery have a faster recovery of erectile function then patients after open surgery.

Study design

Patients are randomised at the time of inclusion: Group 1 starts immediately with therapy, group 2 only after 3 months.

Patients are evaluated at the time of inclusion, at the time of starting the therapy phase, after 3 months of therapy and 3 months after the end of the therapy.

Intervention

Patients, who still suffer from erectile dysfunction, 12 months after surgery, will be randomised in group 1 (starting immediately with pelvic floor muscle exercises) or in group 2 (starting 3 months later with pelvic floor muscle exercises). 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. 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. Male patients, who had an unilateral/bilateral nervesparing open or robot radical prostatectomy at least 12 months earlier and still suffer from erectile dysfunction;

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

3. Patients who are willing to quit additional medication, like PDE-5 inhibitors, intracavernous

injections during the entire study period.

Exclusion criteria

1. Patients, who didn't have erections and/or sexual intercourse preoperatively;

2. Patients, who underwent a nonnerve sparing radical prostatectomy;

3. Patients , who are not willing to quit additional medication, like PDE-5 inhibitors, intracavernous injections during the entire study period;

4. Patients, who are not able to perform pelvic floor muscle exercises because of cognitive problems;

5. Patients who refuse to participate in the study.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2011
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-12-2011
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	NL3032
NTR-old	NTR3180
Other	: ML7136
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A