Urethral suspension using vas deferens for prevention of urine incontinence after robot-assisted laparoscopic prostatectomy (RALP)

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Improve postoperative urine continence after prostatectomy for prostate cancer.

Ethical review	Approved WMO
Status	Pending
Health condition type	Urinary tract signs and symptoms
Study type	Interventional

Summary

ID

NL-OMON33954

Source
ToetsingOnline

Brief title
VDUS = vas deferens urethral support

Condition

- Urinary tract signs and symptoms
- Renal and urinary tract therapeutic procedures

Synonym
urine incontinence, urine spill

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: start geld

Intervention

Keyword: prostate, prostatectomy, urine incontinence

Outcome measures

Primary outcome

Urine continence at 3 and 6 months postoperatively assesed using questionnaires

and the urine pad test.

Secondary outcome

Urine retention and bladder/urethra anastomosis stricture formation and urine

leakage at cystogram and erectile function recovery.

Study description

Background summary

Urine incontinence is a relatively frequent problem after prostatectomy. Most men have problems retaining urine in the first months after surgery. In the first 6 to 12 months the majority of men experience urine loss to some degree. Possible explanations are mentioned neuropraxia of pelvic floor muscles, denervation of the proximal urethra, local damage to the musculature of the pelvic floor, and the loss of the urethral closure mechanism by the prostate. Although urine continence recovers in most men after several months. Several methods have been applied to prevent early urine incontinence. Moreover, secondary (suspension) procedures of the urethra have been suggested to treat postprostatectomy urine incontinence. The current study evaluates the use of urethra support by a suburethrale placed vas deferens to prevent early postprostatectomy urine incontinence.

Study objective

Improve postoperative urine continence after prostatectomy for prostate cancer.

Study design

A randomized prospective analysis with single-blind design (the surgeon can not be blinded). Patients will not be informed on the selected treatment.

Intervention

After the prostatectomy procedure men will be intraoperatively randomized between the vas deferens urethral support (VDUS) procedure or standard anastomosis. VDUS will be performed by isolation of 15cm of vas deferens isolated from the right or left parailiac region. The vas section will be used as a sling underneath the proximal membranous urethra and fixed to the pubic bone on both sides. A 60cm H2O tension will be applied prior to fixation of the vas deferens to the pubic bone.

Study burden and risks

The prostatectomy procedure will be prolonged by an estimated 10 minutes for the VDUS procedure. After a prostatectomy the vas deferens is no longer functional and can be used for suspension. Early results from perineal suspension methods showed risk of urine retention after suspension over 60cm of H2O pressure. For this reason suspension will be limited to this level of urethral pressure as described above. In the case of postoperative retention requiring recatheterisation it can be expected that with time the vas difference will dissolve considering the fact that it is fully disconnected from its blood supply. This will probably occur within several months. If no sufficient urine passage is acquired by that time, a bladder neck incision is feasible without extra risk for urethral sphincter damage considering the fact that the suspension will be positioned at the bladder neck rather than the urethral sphincter.

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

= localized prostate cancer treated with prostatectomy
= normal preoperative urine continence

Exclusion criteria

= earlier prostatic surgery such as TURP
= non-dutch speaking men
= inability to understand informed consent

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2009
Enrollment:	94
Type:	Anticipated

Ethics review

Approved WMO
Application type: First submission

Review commission: PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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
CCMO	NL26125.031.09