Non-invasive evaluation of urinary bladder contractility and urethral resistance after ProACT treatment of stress urinary incontinence in men: a pilot study.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21192

Source
NTR

Health condition

stress urinary incontinence
urine stress incontinentie

Sponsors and support

Primary sponsor: Erasmus Medical Center, Department of Urology
Source(s) of monetary or material Support: Erasmus Medical Center, Department of Urology

Intervention

Outcome measures

Primary outcome

From invasive pressure flow study (if applicable):

1. Urethral resistance parameters (BOOI (Bladder Outlet Obstruction Index));

2. Bladder contractility parameters (Wmax (maximum bladder contractility)).

From non-invasive condom catheter measurements:

1. Isovolumetric bladder pressure (Pcond.max);

2. URR (urethral resistance); an experimental non-invasive measure for bladder outlet obstruction, calculated from the
maximum condom pressure (Pcond.max) and the maximum free flow rate.

Secondary outcome

From free flow-rate measurement:

1. Maximum urinary flow-rate;

2. Voided volume.

From invasive pressure flow study (if applicable):

1. Detrusor pressure at maximum flow-rate;

2. Maximum flow-rate;

3. Urethral resistance parameters (URA (Urethral Resistance Factor), Average and slope of lowest part of PURR (Passive Urethral Resistance Relation));

4. Bladder contractility parameters (BCI (Bladder Contractility Index)).

From non-invasive condom catheter measurements:

1. Maximum flow-rate;

2. Residual urine volume measured by transabdominal ultrasound;

3. IPSS (International Prostate Symptom Score) questionnaire;

4. QoL questionnaire.

Study description

Background summary

ProACT (Prostate Adjustable Continence Therapy) is a therapy used to treat male stress urinary incontinence after
prostatectomy. Too high urethral resistance caused by the balloons can result in a thickened bladder wall with urge
symptoms. In order to diagnose this condition, patients undergo a urodynamic investigation after they are subjectively dry.

This invasive measurement can cause several complications, like lower urinary tract infections and haematuria. The Condom Catheter Method is a newly developed and validated method to assess urinary bladder contractility noninvasively.

In combination with a free-flow rate, it can also be used for diagnosing bladder outlet obstruction. This study
compares the invasive urodynamic method with the non-invasive method to evaluate the effect of ProACT implantation in men with incontinence after radical prostatectomy.

The aim of the study is to investigate the possibility of the use of non-invasive methods for the evaluation of
bladder outlet obstruction after ProACT device implantation by comparing non-invasive measurements with invasive
measurements. The ultimate aim is to use non-invasive urodynamics in stead of invasive urodynamics for the follow up of patients implanted with ProACT.

Study design:

Patients will be invited to undergo the non-invasive condom catheter measurement. A free flow measurement is followed
by two measurements with the condom catheter. During voiding flow is interrupted mechanically. De maximal condom pressure reflects the isovolumetric bladder pressure. The non-invasive measurement will be compared with the invasive measurement patients already receive.

Study population:

Fifty men implanted with Pro-ACT for stress incontinence after radical prostatectomy will be invited to participate in the study.

Study objective

The aim of the present study is to investigate the possibility of the use of non-invasive methods for the evaluation of
bladder outlet obstruction after ProACT device implantation by comparing non-invasive measurements with invasive
measurements. The ultimate aim is to use non-invasive urodynamics in stead of invasive urodynamics for the follow up of patients implanted with ProACT.

Study design

When subjectively dry after ProACT implantation for post-prostatectomy incontinence.

Intervention

Non-invasive measurement of the urinary bladder pressure.

Contacts

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Eligibility criteria

Inclusion criteria

1. Male ≥ 18 years of age;

2. Subjectively dry after ProACT implantation for post-prostatectomy incontinence;

3. Mentally and physically able to visit the outpatient clinic;

4. Signed informed consent.

Exclusion criteria

1. Unable to urinate in a standing position;

2. Maximum urinary flow rate below 5 ml/s;

3. Previous lower urinary tract surgery, except prostatectomy and ProACT implantation;

4. Congenital disease of the lower urinary tract;

5. Heart failure.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-04-2010
Enrollment:	50

Type: Actual

Ethics review

Positive opinion
Date: 28-05-2010

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 34897
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2221
NTR-old	NTR2346
CCMO	NL31230.078.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON34897

Study results

Summary results
N/A