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

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bladder and bladder neck disorders (excl calculi)
Study type	Observational non invasive

Summary

ID

NL-OMON34897

Source
ToetsingOnline

Brief title
Non-invasive urodynamics after Pro-ACT.

Condition

- Bladder and bladder neck disorders (excl calculi)

Synonym
involuntary urine loss due to increased abdominal pressure., stress urinary incontinence

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: * Non-invasive urodynamics, * Pro-ACT, * Radical prostatectomy, * Stress urinary incontinence

Outcome measures

Primary outcome

From invasive pressure flow study (if applicable):

• Urethral resistance parameters (BOOI (Bladder Outlet Obstruction Index))

• Bladder contractility parameters (Wmax (maximum bladder contractility))

From non-invasive condom catheter measurements:

• Isovolumetric bladder pressure (Pcond.max)

• 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. [9]

Secondary outcome

From free flow-rate measurement:

• Maximum urinary flow-rate

• Voided volume

From invasive pressure flow study (if applicable):

• Detrusor pressure at maximum flow-rate

• Maximum flow-rate

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

• Bladder contractility parameters (BCI (Bladder Contractility Index))

From non-invasive condom catheter measurements:

• Maximum flow-rate

• Residual urine volume measured by transabdominal ultrasound

• IPSS (International Prostate Symptom Score) questionnaire

• 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 non-invasively. 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.

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

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 burden and risks

In a previous study "A longitudinal non-invasive study of changes in urinary bladdercontractility secondary to prostatic enlargement" (MEC 202.680/2001/148) the noninvasive study method has been applied to 1073 participants. Thus far, the following complications have occurred:
1. Urinary retention in one subject. The investigation did not seem to be the only factor contributing to the occurrence of this condition. Insofar as the investigation has been a contributing factor, this seems to be avoidable if subjects adhere to the instructions given during the investigation.
2. Urinary tract infection in 1 subject. Treated by antibiotics.
3. Slight, self-limiting macroscopic haematuria in 67 subjects (7%). The subjects were advised to drink water. No additional treatment was given.

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

• Male >= 18 years of age
• Subjectively dry after ProACT implantation for post-prostatectomy incontinence
• Mentally and physically able to visit the outpatient clinic
• Signed informed consent

Exclusion criteria

• Unable to urinate in a standing position
• Maximum urinary flow rate below 5 ml/s
• Previous lower urinary tract surgery, except ProACT* implantation
• Congenital disease of the lower urinary tract
• Heart failure
• Use of anticoagulants

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

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

Ethics review

Approved WMO Date:	26-03-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 21192
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL31230.078.10
OMON	NL-OMON21192