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

Gepubliceerd: 28-05-2010 Laatst bijgewerkt: 19-03-2025

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....

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21192

Bron
NTR

Aandoening

stress urinary incontinence
urine stress incontinentie

Ondersteuning

Primaire sponsor: Erasmus Medical Center, Department of Urology
Overige ondersteuning: Erasmus Medical Center, Department of Urology

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Non-invasive measurement of the urinary bladder pressure.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	15-04-2010
Aantal proefpersonen:	50
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	28-05-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 34897
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2221
NTR-old	NTR2346

Register	ID
CCMO	NL31230.078.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON34897

Resultaten

Samenvatting resultaten
N/A