

Validation of single sensor urethral catheter in demonstrating urethral pressure variations during filling cystometry

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To validate the use of single urethral sensor catheter in demonstrating urethral pressure variations during filling cystometry Incidence of significant urethral pressure variations during urodynamic filling phase measured with three urethral sensor...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Urethral disorders (excl calculi)
Study type	Observational invasive

Summary

ID

NL-OMON40650

Source

ToetsingOnline

Brief title

Validation of single sensor catheter for urethral pressure variations

Condition

- Urethral disorders (excl calculi)

Synonym

urethral pressure variations, urgency

Research involving

Human

Sponsors and support

Primary sponsor: Bronovo Ziekenhuis

Source(s) of monetary or material Support: unrestricted grant Astellas Pharma

Intervention

Keyword: catheter, sensor, urethra pressure, urodynamics

Outcome measures

Primary outcome

Primary endpoint is the reproduction of urethral pressure variations, demonstrated with three-sensor catheter, with use of a single-sensor catheter during filling cystometry.

Secondary outcome

none

Study description

Background summary

During the filling (urine storage) phase of a urodynamic investigation (= investigation to measure bladder function or dysfunction, which explains the pathophysiology of the symptoms), urethral (bladder outlet) pressure variations can be observed in a proportion of patients. The clinical relevance and or the role of urethral pressure variations in the pathophysiology are yet not precisely established.

In the literature, urethral pressure variations have been discussed with the use of a catheter with single sensor or three-sensor in the urethra. However, there are very few hospitals using a multiple-sensor catheter. In the gross majority, a catheter with only one sensor in the urethra is used. If clinical relevance of urethral pressure variations is to be further examined, the demonstrating of this condition has to be more widely applicable.

Study objective

To validate the use of single urethral sensor catheter in demonstrating urethral pressure variations during filling cystometry
Incidence of significant urethral pressure variations during urodynamic filling phase measured with three urethral sensor catheter versus measurement with

single urethral sensor catheter

Study design

Prospective observational intervention cohort study. Every adult female patient undergoing urodynamic testing will receive information of this study and will be asked to participate. When informed consent is obtained, the second measurement series will be performed with a single-sensor urethral catheter

Study burden and risks

During urodynamic testing usually two series of filling and voiding cystometry are performed, to be able to reproduce and measure burden symptoms of the patient. To validate the use of a single-sensor catheter, the three-sensor catheter has to be removed after the first series and an extra introduction of the single-sensor urethral catheter has to be performed

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

- Female
- > 18 years of age
- Mentally fit to consent
- Indication for urodynamic testing
- Signed informed consent

Exclusion criteria

none

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 31-05-2016

Enrollment: 76

Type: Actual

Medical products/devices used

Generic name: urodynamic catheter

Registration: Yes - CE intended use

Ethics review

Approved WMO

Date: 23-03-2015

Application type: First submission

Review commission: METC Leids Universitair Medisch Centrum (Leiden)

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	NL50168.058.14

Study results

Date completed: 12-07-2018

Actual enrolment: 75

Summary results

Trial is ongoing in other countries