# 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 cystometryIncidence of significant urethral pressure variations during urodynamic filling phase measured with three urethral sensor...

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|---|---|
| **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

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|---|---|
| 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

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|---|---|
| Date completed: | 12-07-2018 |
| Actual enrolment: | 75 |

**Summary results**
Trial is onging in other countries