Validatie van meting met enkele urethrale druksensor in het aantonen van drukvariaties in de urethra tijdens vullings cystometrie

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26027

Source
Nationaal Trial Register

Brief title
VALUPRES

Health condition

Urodynamics in female patients with lower urinary tract symptoms (LUTS)

Sponsors and support

Primary sponsor: LUMC
Source(s) of monetary or material Support: unrestricted research grant Astellas Pharma

Intervention

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

n.a.

Study description

Background summary

Rationale: 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 sensors in the urethra. However, there are very few hospitals using a multiple-sensor urethral 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.

Objective: To validate the use of single urethral sensor catheter in demonstrating urethral pressure variations during filling cystometry
Study design: Prospective observational intervention study.

Study population: Adult female patients, mentally fit to consent, undergoing urodynamic evaluation.
Intervention: Removal of three-sensor catheter and introduction of a single-sensor catheter for the second measurement series during urodynamic evaluation.

Main study parameters/endpoints: Primary endpoint is the reproduction of urethral pressure variations, demonstrated with three-sensor catheter, with use of a single-sensor catheter during filling cystometry.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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.

Study objective

To validate the use of single urethral sensor catheter in demonstrating urethral pressure variations during filling cystometry

Study design

one timepoint, the day/date of urodynamic evaluation

Intervention

Removal of three-sensor catheter and introduction of a single-sensor catheter for the second measurement series during urodynamic evaluation

Contacts

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Eligibility criteria

Inclusion criteria

Every female patient scheduled for urodynamic evaluation

Exclusion criteria

none

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2016
Enrollment:	75
Type:	Anticipated

Ethics review

Positive opinion

Date:	25-01-2018
Application type:	First submission

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
NTR-new	NL6823
NTR-old	NTR7009
Other	CME nummer // NL nummer : P14.257 // NL50168.058.14

Study results