In Vivo Comparison of Air Charged Catheters with Water Filled Catheters for Intravesical and Intrarectal Pressures Recording during Urodynamic Testing.

Published: 08-07-2013
Last updated: 24-04-2024

Objective: To compare the in vivo pressure responses of air-charged catheters with water filled catheter systems pressure responses during standard cystometry.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Urinary tract signs and symptoms
Study type	Observational invasive

Summary

ID

NL-OMON39662

Source
ToetsingOnline

Brief title
Comparison AC-WFpressures

Condition

- Urinary tract signs and symptoms

Synonym
lower urinary tract dysfunction; urinary incontinence, voiding dysfunction

Research involving
Human

Sponsors and support

Primary sponsor: T-doc-LLC
Source(s) of monetary or material Support: opdrachtgever/ verrichter Tdoc zie B6-7

Intervention

Keyword: Good urodynamic practice, Measuring techniques, Urodynamic testing

Outcome measures

Primary outcome

Main study parameters/endpoints: Difference of intravesical pressure increment maximum during filling cystometry between the two systems.

Secondary outcome

Difference (cmH2O) between air charged and water filled systems in intravesical pressure cough maximum (peak) amplitude during filling cystometry (for patients able to cough).

Difference (cmH2O) between air charged and water filled systems in intravesical pressure standard strain to 50cmH2O (on water filled system) increment maximum during filling cystometry (for patients able to strain).

Difference (cmH2O) between air charged and water filled systems in intrarectal pressure standard strain to 50cmH2O in intravesical pressure on water filled system increment maximum during filling cystometry (for patients able to strain).

Difference (cmH2O) between air charged and water filled systems in intravesical pressure overactive contraction increment duration (return to baseline) during filling cystometry.

Difference between both systems in the number of small amplitude (* 5cmH2O) intravesical pressure events during filling.

Qualitative difference in pattern of spontaneous rectal activity

Qualitative difference in pattern of -one per investigation- provoked tube

kicking artefact in both systems

Study description

Background summary

PROTOCOL TITLE: In Vivo Comparison of Air Charged Catheters with Water Filled Catheters for Intravesical and Intrarectal Pressures Recording during Urodynamic Testing

Rationale: Various systems to measure intravesical and intrarectal pressure during urodynamic testing; especially cystometry, exist. Water filled tube -systems are the most commonly used and should be regarded as the contemporary standard. A water filled system is however sensitive to tube and or patient movement artefacts and prone to erroneous calibration. Air charged catheters are less sensitive to patient and especially tubing- movements, and calibrate easier. However, in vitro tests have demonstrated that air charged catheters respond somewhat slower and relatively damped, especially to rapid pressure changes as in (simulated) coughing, in comparison with water filled systems. The clinical relevance of these observations is unknown. To compare the technical reliability and clinical applicability of the two types of catheter systems for cystometry an in vivo double catheter testing procedure, in a prospective group or patients scheduled for urodynamic investigation is the necessary step, following on to the in vitro tests.

Study objective

Objective: To compare the in vivo pressure responses of air-charged catheters with water filled catheter systems pressure responses during standard cystometry.

Study design

Study design: Prospective patient cohort monocenter double urodynamic technique study.

Study burden and risks

Both catheter systems that are compared in this study are marketed and safe for intended routine use. Only patients that are scheduled for urodynamic investigation on the basis of standard clinical practice protocols and guidelines are recruited for this study.
For this scientific study we will introduce a standard 6F (=2 mm diameter) single lumen transurethral intravesical catheter synchronously with an extra 7F

(2,3 mm diameter) air charged transurethral intravesical catheter and also a standard 10F (3,3 mm diameter) transanally inserted intrarectal rectal tube synchronously with an extra intrarectal (7F) air charged catheter. These extra catheters cause only minimal (if any) extra burden because the catheters are introduced together (side by side). Furthermore lubricating (lidocaine) anaesthetic gel is instilled in the urethra before insertion of the catheters as a routine. Any extra sensation or harm is not expected, not in the female urethra that has usually a diameter of 30F (10 mm) and also not in the neurologically affected (male of female) patients with spinal cord injury or meningomyelocele that have no lower urinary tract sensation at all. This lack of relevant extra burden due to catheterisation transurethrally, is even more pertinent for the intrarectal catheters.
It is unlikely that the catheterisation as employed in this study produces an extra risk for haematuria or urinary tract infection.
It is not expected that the double system cystometry influences the clinical result in any manner therefore the inclusion of (normal) volunteers is unnecessary.

Results obtained in the selected patients are scientifically relevant and generalizable to all patient categories usually scheduled for urodynamic testing and will have consequences for the clinical practice care of future patients.

Contacts

Public
T-doc-LLC

Edgemoor Road 181
Wilmington DE 19802
US
Scientific
T-doc-LLC

Edgemoor Road 181
Wilmington DE 19802
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

2 sets of criteria follow: for 'all female' and for all persons with neurogenid dysfunction.;Female >18 years
Scheduled for urodynamic investigation on the basis of contemporary standards and guidelines, because of signs and symptoms of lower urinary tract dysfunction.
*May perform (not excluded) intermittent (self) catheterisation.
No signs of voiding dysfunction (routine outpatient max flow >20mL/s without significant (>100mL)postvoid residual)
No signs of bladder /pelvic pain syndrome;OR:
Male or female >18years
Complete spinal cord injury, level above T12, or meningomyelocele unable to void and significantly reduced or no pelvic floor, urethral and or bladder sensation.
* May have (not excluded) *sacral sparing*; some residual anal sensation
Scheduled for urodynamic investigation on the basis of contemporary standards and guidelines, because of signs and symptoms of lower urinary tract dysfunction or because of routine (protocol, guidelines) follow -up.
* (Usually: performing intermittent (self) catheterisation); not excluded.
* May have (not excluded) chronic indwelling catheter.

Exclusion criteria

One (or more) of the following necessitates exclusion of the patient:;Male with normal lower urinary tract sensation.;Unwilling or unfit to sign informed consent.
ASA >2; Karnovski <80%.;Women with voiding dysfunction
Patients included in other scientific studies (for other reasons).

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):	16-03-2015
Enrollment:	36
Type:	Actual

Medical products/devices used

Generic name:	Tdoc air charged urodynamic catheter
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	08-07-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
Other	Clinical Trials Gov: Pending
CCMO	NL42098.041.13