

Nonmicturation bladder activity in relation to selfconsciousness during filling phase and sensation measurement during filling phase

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Ethical review	-
Status	Recruiting
Health condition type	Bladder and bladder neck disorders (excl calculi)
Study type	Observational invasive

Summary

ID

NL-OMON32252

Source

ToetsingOnline

Brief title

Nonmicturation bladder activity during filling phase

Condition

- Bladder and bladder neck disorders (excl calculi)

Synonym

Detrusor overactivity, Overactive bladder syndrome

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Ziekenhuis Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: activity, Bladder, non micturition, overactive

Outcome measures

Primary outcome

Primary Objectives

- To characterise non-micturition activity during normal bladder filling
- To determine the nature of any change in this activity associated with OAB
- To relate this activity to bladder volume and sensation.
- To demonstrate the micromotions
- To study the link between OAB and micromotions in relation to bladder neck obstruction

Secondary outcome

Secondary objectives

- To identify possible mechanisms underlying OAB
- To gain ideas for a better treatment for OAB
- To explore the possibility that therapeutically important drugs for OAB exert their action via inhibition of non-micturition activity

Study description

Background summary

The sensation of the need for urination (urge) is a complex and only partially understood mechanism. It is our hypothesis that this mechanism is disrupted in

patients suffering from overactive bladder syndrome.

The Overactive Bladder syndrome (OAB) has been defined as a spectrum of symptoms in which incontinence may or may not overlap with urgency, frequency and nocturia. This syndrome is estimated to affect approximately 17% of the adult population in Europe and the United States. The symptoms of overactive bladder have many potential causes and contributing factors. One of these factors is an outlet obstruction of the bladder due to benign prostatic hyperplasia (BPH). Nowadays antimuscarinic drugs are used for treatment of the overactive bladder. Antimuscarinic agents have been proven to work slightly to moderately better than placebo* and are associated with side effects such as a dry mouth, blurred vision and constipation.

Many patients with lower urinary tract symptoms (LUTS) develop OAB. In this group of patients with LUTS and OAB, there is not always a clear obstruction found. So, at least in some patients, with LUTS, there must be another reason for OAB than obstruction.

The autonomous bladder activity has been introduced by, among others the Maastricht Urology research group. In animal models, the bladder is shown to have rhythmic low amplitude contractions (micro motions). It is hypothesised that this activity has a sensory function in the micturation regulation system which is mainly located in the bladder wall. These so called micromotions have never been demonstrated in the human bladder. The sensing function of the bladder and the micturation reflex remain mainly unclear. We hypothesise that there is a dysregulation of the autonomous bladder activity (micro motions) in patients with OAB.

We want to explore and study the relationship between OAB, obstruction and the micro motions in order to gain a better understanding of the bladder (patho)physiology. This in its turn, can help us in the quest for better treatment strategies for patients suffering from OAB.

Study objective

The study is divided in two distinct groups a male and female group:

The male group consist of patients with lower urinary tract symptoms (LUTS).

The female group consist of patients with the overactive bladder syndrome OAB.

The primary objective of this pilot experiment is to describe via an observational study the relation between non-micturation bladder activity and sensation during the filling phase of the bladders in women. We want to explore if there is a relation between non-micturation bladder activity and the sensation of urgency during the filling phase.

Furthermore in men, we want to study the relationship between non-micturation bladder activity and the amount of obstruction.

We would also like to visualize the micro motions of the bladder in both men and women during filling phase and study the influence of (visual and cognitive) stimuli on bladder activity.

We want to explore if there is a relation between non-micturation bladder

activity and the sensation of urgency during the filling phase in male patients with Lower urinary tract symptoms. In order to gain a better understanding in bladder (patho)physiology.

Study design

A pilot observational study to describe the non-micturation bladder activity and sensation measurement during filling phase.

Study burden and risks

There is no burden on patient taking part in this study other than the extra time spent in the hospital which will be between 30 to 60 minutes.
There are no risks in taking part in this study.

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 patients who will undergo ambulatory urodynamics to investigate their symptoms of urge and frequency (>8 micturitions per day)

Male and female patients with LUTS who will undergo a classic stationary urodynamic measurement to investigate their symptoms of urge and frequency.

Exclusion criteria

None

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 21-10-2008

Enrollment: 100

Type: Actual

Ethics review

Not available

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	NL22285.068.08