The effect of position (sit/stand up vs supine position) on urge sensation in volunteers and in patients with overactive bladder syndrome

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The primary objective of this experiment is to describe via an observational study the relation between conditions of sitting/standing up versus laying down in terms of bladder sensation in both volunteers and patients with OAB. We also want to...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Genitourinary tract disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON35512

Source
ToetsingOnline

Brief title
The effect of position (sit/stand up vs supine position) on urge sensation

Condition

- Genitourinary tract disorders NEC

Synonym
overactive bladder syndrome, urgency

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Ziekenhuis Maastricht

Source(s) of monetary or material Support: NWO mozaiek subside aan drs M.S. Rahnama i

Intervention

Keyword: Bladder, position, sensation, Urge

Outcome measures

Primary outcome

· To study the effect of position on bladder sensation in volunteers and patients with overactive bladder syndrome

· To study the effect of position on voided volumes in volunteers and patients with overactive bladder syndrome

· To study the relationship between bladder sensation and the voided volumes in both volunteers and patients.

Secondary outcome

Secondary objectives

· To characterise self consciousness in patients with OAB

· To characterise the difference between volunteers and patients with OAB in regards to self consciousness and bladder perceptions

· To characterise the difference between men and women in regards to self consciousness and bladder perceptions.

· To determine the relationship between self-consciousness and bladder perceptions in patients with OAB

· To determine the relationship between the functional bladder capacity and OAB

symptoms in relation to patient perception

· To relate voided volumes to patient perception.

· To study the link between OAB symptoms and patient bother from OAB to self

consciousness and bladder perception

· To study the relationship between the functional and maximal bladder capacity

in relation to OAB symptoms and bother in OAB patients.

Study description

Background summary

We would like to study the regulation mechanism of the bladder. This is in the light of finding new treatment strategies for OAB. Patients suffering from OAB have symptoms of urgency and/or frequency.
according to recent studies the prevalnce of OAB is about 17 % of the population opver 40 years , in the western world
We would like to study the relationship between position and bladder sensation in both OAB patients and healthy volunteers.

Study objective

The primary objective of this experiment is to describe via an observational study the relation between conditions of sitting/standing up versus laying down in terms of bladder sensation in both volunteers and patients with OAB.
We also want to explore if there is a relation between bladder volume and the sensation of urgency.
Furthermore we would like to study the level of self-consciousness and bladder filling correlated to voided volumes and the perception of the sensation during the filling phase of the bladders in these patients

We want to explore if there is a relation between the postural position, the bladder filling, the volume voided, the trait and state level of patient self-consciousness and the sensation of urgency during the filling phase in these patients with OAB.

Study design

Group 1. OAB Patients:
Patients will be recruited from our patient pool of the urology department.

That means known or new patients from our out patient clinic in Maastricht diagnosed with OAB. Patients will be asked to go to a toilet and empty their bladder on inclusion at the outpatient clinic. The residual volume in the bladder will be assessed. All patients with a post voidal residu of more than 100 cc will be excluded from the study. Since this will influence the urge sensations and therefore the study outcome.
All patients using anticholinergic medication will be asked to stop taking their anticholinergic for at least 10 days prior to the study date to eliminate the effect of anticholinergics on urge sensations.

The inclusion criteria for patients is > 8 micturitions per day, and a minimum of one episode of urgency per day).There will be no catheter insertion or any medication used. After receiving detailed information about the study and receiving informed consent, patients will be asked to come to our outpatient clinic (urology function room) after drinking 1 litre of water (SPA blauw) at home prior to arrival. At arrival patients will be asked to fill in a self consciousness questionnaire which will take about 5 minutes. Then they will be asked to drink another 0.5 litre of water and drink additional 250 ml of water every 15 minutes in our clinic for one hour. We will wait for them to void when they can in a special toilet that can measure the amount of urine flowing in it.
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From that urine, a sedimentation test will be done in order to assess if there is any ongoing urinary infection, which can influence our study data. After voiding the patients residual urine volume will be assessed, non-invasively by an ultra sound scan 3D echo. Every 10 minutes participants are asked to change posture (lying down or standing up). Just before and just after this posture change they grade their bladder sensation at that time point. For that purpose we will use a special visual analogue scale (VAS) on which the patient can point out his feeling in a scale running from no sensation at all to very strong voiding sensation. Furthermore they will be asked to complete a seven-item VAS-scale that measure different aspects of level of state self-consciousness. Patients will be asked to keep their urine as long as possible and only void at a strongest urge sensation they can withstand.

. When they can*t hold the urine any longer, they will void in the toilet and their voided volume will be measured. And again an ultrasound bladder scan will be conducted to assess the residual volume post micturition. This whole session will take between 60 to 120 minutes depending on the patients functional bladder capacity and the time that he can hold up his urine.

The study procedure will be performed two times on two different days within a time period of 10 days.

Group 2. volunteers without OAB symptoms.
Volunteers will be recruited by means of a newspaper add or a poster. After receiving detailed information about the study and receiving informed consent, these volunteers will be asked to come to our outpatient clinic (urology function room). Subsequently they will be subjected to the exact same protocol as Group 1.

Study burden and risks

There are no direct riscs in taking part of this study. stopping anticholinergic medicatioon might re introduce the patients voidning complaints but these complaints will dissappear after restarting the medication. Drinkng large amounts of water might be dangerous to patients with congestive heartfailure, therefore these patients are excluded from 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

Patient arm: patients older than 18 years with OAB diagnosed by their urologist using the criteria of more than 8 micturitions on three consecutive days of these three days they keep a micturation diary with a VAS score for urge sensation. Patients should have at least one episode of urge: sudden compelling desire to void which can not be postponed.
Volunteers arm: volunteers older than 18 years are considered eligible if they have no urologic history or urinary complaints.

Exclusion criteria

Patient arm: congestive heart disease or history of heart failure; patients on anticholinergic medication that are not willing to stop this medication; presence of post void residual urine > 100cc determined by ultrasound; presence of urinary tract infection, determined by urine sticks. Patients with urinary tract infection will be treated by antibiotics. After resolution of the infection, the patient can re-enter the study if the urine is sterile at that moment.
Volunteer arm: urinary complaints or urologic history; congestive heart disease or history of hear failure; presence of postvoid residual urine > 100cc determined by ultrasound; presence of urinary tract infection, determined by urine sticks. Volunteers that present with urinary tract infection will be definitively excluded from participation.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-04-2009

Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	11-02-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	12-04-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL25982.068.08
Other	volgt