Increasing diuresis rate in patients with Overactive Bladder symptom complex as a possible treatment

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1) Is the difference in diuresis between patients and volunteers caused by a dept in water household in patients and if so can we increase the diuresis in patients by correcting this?2) Can we influence the pattern of bladder sensations by…

Ethical review	Not approved
Status	Will not start
Health condition type	Bladder and bladder neck disorders (excl calculi)
Study type	Observational non invasive

Summary

ID

NL-OMON36221

Source
ToetsingOnline

Brief title
Increasing diuresis as treatment of overactive bladder symptom complex

Condition

- Bladder and bladder neck disorders (excl calculi)

Synonym
Overactive Bladder, Urgency

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: diuresis, Overactive Bladder, treatment, waterload protocol

Outcome measures

Primary outcome

Increase diuresis rates within patients suffering from OABsc by advising them to drink more during daytime.

Evaluate whether this higher diuresis induces a changed velocity of intensification of bladder sensations (as a result: change the curve drawn while following a physiological bladder filling following a water load protocol) in patients.

Secondary outcome

Treat symptoms of patients suffering OABsc by means of altering (increasing) their diuresis velocity.

Study description

Background summary

The average natural forced diuresis for patients (mean 6.90, SD 2.8 ml/min) is significantly lower than the diuresis for volunteers (mean 12.1, SD 3.4 ml/min) ($p<0.001$).This could mean that patients had a deficit in water household, probably because their drinking behaviour was different from the healthy volunteers. We know people with OABsc drink less than healthy volunteers because drinking has been associated by the patients with need to go to the toilet.
However we hypothesize that patients could get a development of bladder sensations more similar to healthy volunteers when their diuresis velocity increases. The clinical relevance of this hypothesis can be that we can help patients with OABsc to make their urgency and intensity of sensations develop different (e.g. more equal to healthy volunteers) and maybe get rid of a component of their symptoms. This hypothesis will be the tested in our future

study.

Study objective

1) Is the difference in diuresis between patients and volunteers caused by a dept in water household in patients and if so can we increase the diuresis in patients by correcting this?
2) Can we influence the pattern of bladder sensations by increasing the diuresis in patients with OABsc?

Study design

We have to gain information about the baseline of sensation-development during bladder filling for al the patients when diuresis is assumed to be *not optimal*; this means a suspected diuresis rate lower than the diuresis in healthy people. Afterwards we have to conduct information about the development of the bladder sensations when diuresis rate has increased and approaches diuresis rate of healthy volunteers. This will be done by organising 2 (group)sessions for all patients: session 1: normal intake; session 2: higher intake. The principal investigator will be present during the sessions.
Before every session each subject will be asked to drink 1000 ml of water in the hour before the session begins to establish a normal but elevated diuresis. On arrival at the session the subject will be asked to void and continue drinking a further 1000 ml through out the session (200 ml per 10 minutes). This water load will facilitate urine production and bladder filling reaching a capacity over approximately 1-2 hr period (numbers based on our preliminary work).
During the normal intake session (about 1 hour) the patients are asked to record their sensation and grade it every 10 minutes (see appendix1). Moreover they are asked to fill in this sensation on an empty curve (appendix2) which we developed during the focus-group study and with which we objectivised the different shapes of curves between patients and healthy subjects. For each subject the bladder capacity at maximum sensation will be determined by measuring the urine volume voided at the end of the session. Afterwards we can calculate the diuresis velocity during this first session.

Study burden and risks

No risks.
Patients may benefit because we hypothesise that their symptoms may alter en decrease after drinking more and getting rid of their deficit in waterhousehold.

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

Patients with OAB diagnosed by their urologist using the criteria of more than 8 micturitions on three consecutive days. While investigation starts they will not use any anticholinergic or other therapy. Patients on anticholinergic therapy will be asked to stop this therapy for at least 10 days before they enter the first session. Well versed in Dutch.

Exclusion criteria

Congestive heart disease or history of heart failure
Presence of urinary tract infection. These patients will be treated by antibiotics.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Ethics review

Not approved

Date:	22-06-2011
Application type:	First submission
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	NL36836.068.11