

# 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...

<b>Ethical review</b>	Not approved
<b>Status</b>	Will not start
<b>Health condition type</b>	Bladder and bladder neck disorders (excl calculi)
<b>Study type</b>	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 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

CCMO

### ID

NL36836.068.11