

# Prevention of lower urinary tract symptoms in elderly males: the effects of an increased urine output on symptoms and bladder functioning

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<b>Registration date</b> 20/02/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 03/08/2009	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

## Study information

### Scientific Title

### Study objectives

Increasing the urine output will lead to improved bladder function and to a decrease in symptom severity.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approval received by the ethical review board of the Maastricht University/University Hospital Maastricht on the 8th December 2002 (ref: MEC-00-155).

### Study design

Randomised active controlled parallel group trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Other

### Study type(s)

Prevention

### Participant information sheet

### Health condition(s) or problem(s) studied

Prostate Cancer, Lower Urinary Tract Symptoms (LUTS)

### Interventions

The study population was recruited via 21 general practices.

The General Practitioners (GPs) invited their total male population between 55 and 75 years of age to participate. A screening questionnaire, containing the International Prostate Symptom Score (IPSS; range zero to 35), questions on co-morbidity, and a 24-hours drink diary, together with the informed consent documents, were enclosed with the doctor's invitation.

People in the intervention group were advised to drink 1.5 litres of water per day, additional to their normally consumed beverages, for a period of six months. They were advised to divide this amount into three portions of 0.5 litre spread over the day. To improve the adherence to the

intervention they were supplied with 0.5 litre glasses. The control group received a placebo intervention in the form of syrup (one tablespoon [8 ml] each day during dinner), also for a period of six months.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

Maximum Uroflow, measured in ml/s Symptoms, measured with the International Prostate Symptom Score (IPSS).

**Secondary outcome measures**

1. Perceived benefit of the intervention, seven-point scale (ranging from "much worse" to "much better")
2. Isovolumetric maximum bladder pressure, measured with non-invasive extrenal condom catheter method
3. Bladder wall thickness, measured ultrasonografically by measuring the thickness of the anterior bladder wall

**Overall study start date**

15/06/2000

**Completion date**

15/06/2003

**Eligibility****Key inclusion criteria**

1. Males, aged between 55 and 75 years of age
2. Gave informed consent
3. Screened for moderate Lower Urinary Tract Symptoms (LUTS) (International Prostate Symptom Score [IPSS] : eight to 19)

**Participant type(s)**

Patient

**Age group**

Senior

**Sex**

Male

**Target number of participants**

141

**Key exclusion criteria**

The main exclusion criteria were:

1. The presence of mild (IPSS-score: zero to seven) or severe (IPSS-score: 20 to 35) LUTS
2. A self reported fluid intake above 2 litres per day

Other exclusion criteria were:

1. The presence of diabetes
2. Parkinson's disease
3. Renal diseases
4. Past surgery of the lower urinary tract
5. A history of prostatic or bladder carcinoma
1. The use of diuretics, medication for LUTS, or tricyclic antidepressive agents

We excluded 1673 men on the basis of these criteria. The remaining 238 men were invited for an intake visit and for a baseline assessment. At this point participants were excluded if no baseline assessment was possible (e.g., inability to urinate in the presence of the assessor), if prostate cancer was diagnosed (Prostate Specific Antigen [PSA] more than 4.0 µg/l followed by biopsy that confirmed the presence of a carcinoma), or if they had a serum sodium level below 130 mmol/l.

**Date of first enrolment**

15/06/2000

**Date of final enrolment**

15/06/2003

## **Locations**

**Countries of recruitment**

Netherlands

**Study participating centre**

**University Maastricht (UM)**

Maastricht

Netherlands

6200 MD

## **Sponsor information**

**Organisation**

University Maastricht (UM) (The Netherlands)

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**Sponsor type**

University/education

**Website**

<http://www.unimaas.nl/default.asp?taal=en>

**ROR**

<https://ror.org/02jz4aj89>

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

## **Results and Publications**

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration