ISRCTN91699014 https://doi.org/10.1186/ISRCTN91699014

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

Submission date	Recruitment status	[ ] Prospectively registered
20/02/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/02/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
03/08/2009	Urological and Genital Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr M G Spigt

Contact details
University Maastricht (UM)
CAPHRI Research Institute
PO Box 616
Maastricht
Netherlands
6200 MD
+31 (0)43 388 2309
m.spigt@hag.unimaas.nl

Additional identifiers

Protocol serial number
NCT100; ZonMw: 2100.0070

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

Study type(s)
Prevention

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed
No

Age group
Senior

Sex
Male

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 ìg/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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration