

# LUTS-BPH in general practice, a new approach

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Primary Objective: To answer the following question: Does the extended approach (defined as uroflowmetry and bladder scan after the first consultation, followed by a check-up in month 3 of the male patient over 50 years of age first presenting with...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Genitourinary tract disorders NEC
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON34826

### Source

ToetsingOnline

### Brief title

LUTS-BPH in general practice

### Condition

- Genitourinary tract disorders NEC

### Synonym

benign prostatic obstruction, prostatic enlargement

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Sint Radboud

**Source(s) of monetary or material Support:** AGIS Zorgverzekeringen;aanvraag goedgekeurd

## Intervention

**Keyword:** general practice, LUTS, prostatic hyperplasia, uroflowmetrie and bladderscan

## Outcome measures

### Primary outcome

Number of referrals to urologist in connection with LUTS-BPH symptoms in 12 months

### Secondary outcome

Number of patients on medication (i.e., alpha-blockers or 5-alpha-reductase inhibitors) in 12 months

IPSS-measurement after 12 months

## Study description

### Background summary

The diagnostics and treatment of older men suffering from LUTS/BPH symptoms (Lower Urine Tract Symptoms / Benign Prostate Hyperplasia) comes under first-line health care in accordance with the NHG standard \*Problematic urination in older males\*. LUTS (Lower Urine Tract Symptoms) is an umbrella term for complaints of the lower urinary tract. A distinction is made between obstructive and irritative complaints. These LUTS symptoms may have a number of different causes. In the case of older men, benign prostate hypertrophy is one of the major causes.

Epidemiological research conducted in Rotterdam and Boxmeer shows that 30% of men older than 50 have moderate to severe urinary complaints with an IPSS (International Prostate Symptom Score) higher than seven. The annual GP-surgery incidence rate is 4-9 in every 1,000 men annually in the age category 45-64, rising to 10-18 in every 1,000 men older than 75. Annual prevalence in the age categories referred to above is 8-19 and 36-165 in every 1,000 men respectively.

Although the symptoms can seriously affect the quality of life, they are often accepted: \*It's just part of getting older\*. The Boxmeer study showed that only 17% of men with moderate symptoms and 42% of men with serious symptoms consulted their GPs regarding their symptoms (2).

First-line treatment is conducted as described in the NHG standard \*Problematic urination in older males". If the GP is unable to provide an acceptable solution for the patient, the patient will be referred to the urologist. In the second line of care, more extensive variants of the first-line tests are carried out: blood test, uroflowmetry, a bladder scan and possibly an ultrasound of the prostate. The diagnostics for LUTS-BPH complaints are performed in accordance with the guidelines of the Netherlands Association for Urology, the LUTS-BPH guideline.

As things are now, the GP has no direct access to the uroflowmetry and the bladder scan.

It would be desirable for the GP to be able to conduct these tests independently or, as is the case with lung function tests for example, to be able to request these tests from the medical specialist directly, including an assessment and recommendation from the medical specialist. We know of no literature, however, that describes the value of a uroflowmetry and a bladder scan for first-line health care.

## **Study objective**

Primary Objective:

To answer the following question: Does the extended approach (defined as uroflowmetry and bladder scan after the first consultation, followed by a check-up in month 3 of the male patient over 50 years of age first presenting with LUTS-BPH symptoms in the GP\*s surgery) show a different referral rate , compared with current treatment in accordance with the NHG standard \*Problematic urination in older males\*?

Secondary Objectives:

In the new approach, the use of medication decreases significantly.

## **Study design**

This is an open randomised interventional study.

## **Intervention**

The usual-care group receives treatment according to the NHG standard \*Problematic urination in older males\*. The members of the study group will have a bladder scan and uroflowmetry assessment immediately after the first consultation, on the basis of which the subsequent policy will be determined. Check-up by the GP is to be scheduled in month 3. After 12 months, the participants will receive an IPSS form and a patient satisfaction survey.

## **Study burden and risks**

After the consultation, participating patients from the study group will be invited for a uroflowmetry assessment and a bladder scan. These procedures will be performed by a duly trained assistant. The results will be assessed by a trained GP, and the recommendation sent to the referring GP. The study involves a time investment of 20-30 minutes on the part of the patient. There are no risks associated with this study. Over time, this study may help improve the first-line treatment of patients with LUTS-BPH symptoms.

## 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

All males over 50 registered with one of the GPs associated with the Huisartsenzorg IJsselstein Partnership first presenting with LUTS-BPH symptoms in the GP's surgery

## Exclusion criteria

Man under treatment of an urologist

Man using medication;  $\alpha$ -blocker or 5- $\alpha$ -reductase inhibitor

Man with hematuria, urine-tract infection or abnormal rectal investigation

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

**Primary purpose:** Diagnostic

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2010
Enrollment:	130
Type:	Actual

### Medical products/devices used

Generic name:	uroflowmeter; bladder scan
Registration:	Yes - CE intended use

## Ethics review

Approved WMO	
Date:	26-10-2010
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

## 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	NL29822.091.10