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The use of diagnostic tools for men above 50 years with micturition complaints in general practice

Submission date
22/06/2020

Recruitment status
No longer recruiting

Registration date
30/06/2020

Overall study status
Completed

Last Edited
14/09/2021

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Lower Urinary Tract Symptoms (LUTS) as hesitating, frequency and nocturia are common problems under men above 50 years. LUTS is not caused by the dysfunction the prostate only, but as the disruption of different processes in the bladder, prostate pelvic floor and urethra. Patients are now treated by the guidelines of the Dutch GP's. In general practice, there is a lack of diagnostic tools. Uroflowmetry and ultrasound bladder scanning are important diagnostic tools in LUTS management assessed by the urologist

Who can participate?
Male patients aged 50 and older, who were consulting their GP with lower urinary tract symptoms for the first time.

What does the study involve?
In our study we made two groups; both groups received primary-care treatment involving with or without uroflowmetry and post-void ultrasound bladder scanning. A year after inclusion we counted the referrals to the urologists in both groups. Thereby we asked the participants if they had more or fewer complaints after a year, if they were satisfied with the treatment and if they used medication.

What are the possible benefits and risks of participating?
There were no short time benefits or possibly harms for the participants.

Where is the study run from?
Radboud University Nijmegen Medical Centre (Netherlands)

When is the study starting and how long is it expected to run for?
October 2010 to March 2018

Who is funding the study?
Agis Health insurance, (now Zilveren Kruis Achmea)

Who is the main contact?
H.A. Lammers, hlammers@t-steyn.nl

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
2010/098

Study information

Scientific Title
The usefulness of uroflowmetry and ultrasound bladder scanning as diagnostic tools in primary care for new male patients with lower urinary tract symptoms; a cluster randomized controlled trial

Study objectives
Implementing uroflowmetry and post void ultrasound bladder scanning in primary care for men with LUTS will reduce the number of referrals to urologists.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/10/2010, Medical ethics review committee Arnhem-Nijmegen (Huispost 578, Postbus, 9101, UMC St Radboud Centraal, route 578, Geert Grooteplein 10; +31 24 3613154; cmo@iwkv,ucmn.nl), ref: 2010/098

Study design
Cluster randomized controlled trial

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Lower urinary tract symptoms

Interventions
A cluster randomized controlled trial (RCT) was conducted in general practices in the Netherlands with a total patient population of 24,000. Randomization took place at GP level instead of at patient level to minimize the effects of contamination. A total of 11 GPs were included. Randomization took place in a manual way by the head investigator under control of an independent colleague.

After informed consent, the patients in the intervention group received the usual general practice care with two additional diagnostics tests, namely uroflowmetry and post-void ultrasound bladder scanning, conducted by a trained research assistant under standardized conditions, to assess peak flow and post-void residual volume. The control group received the same care without the two investigations.

The number of referrals to a urologist within 3 and 12 months was assessed with a patient questionnaire.

Intervention Type
Other

Primary outcome(s)
Number of patients referred to urologists within 3 and within 12 months after first consultation measured using patient records

Key secondary outcome(s))
1. Severity of the symptoms measured using IPSS and IPSS-QOL at baseline and one year of follow up
2. Patient satisfaction measured using a Likert scale of 1 to 5 (very dissatisfied to very satisfied) after one year of follow up
3. Urologic medication use (alpha-blocker or 5ARI) measured using patient questionnaire after one year of follow up

Completion date
15/03/2019

Eligibility

Key inclusion criteria

Patients aged 50 and older, who were consulting their GP with LUTS for the first time. LUTS were defined as ‘micturition problems not evidently explained by a specific condition’, in accordance with the definition found in the practice guideline of the Dutch College of General Practitioners

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

Total final enrolment
344

Key exclusion criteria
1. Medication usage (alpha-blockers, 5-alpha-reductase inhibitors or anticholinergics)
2. Previous visits to a urologist because of LUTS
3. Diagnosed or suspected prostate cancer; and a diagnosed urinary tract infection, haematuria or other urologic pathology

Date of first enrolment
01/11/2010

Date of final enrolment
11/03/2018

Locations

Countries of recruitment
Netherlands

Study participating centre
Radboud university medical center
Dept. of Primary and Community Care
Geert Grooteplein 21
Nijmegen
Netherlands
6525 EZ

Sponsor information

Organisation
Radboud University Nijmegen Medical Centre

ROR
https://ror.org/05wg1m734

Funder(s)

Funder type
Industry

Funder Name
Agis Health insurance, (now Zilveren Kruis Achmea)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from H.A. Lammers, email: hlammers@t-steyn.nl. The data includes measurements of all baseline characteristics of the participant: age, results of uroflowmetry and bladder scan, IPSS questionnaire at baseline and after 12 months, satisfaction and medication questionnaires after 12 years of follow up. The data are available from 01/01/2020 until 01/01/2025. Also available are the informed consent and statistical analyses on every reasonable request.). This study was conducted in accordance with the Declaration of Helsinki.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/06/2021	14/09/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes