Lower urinary tract symptoms (LUTS) in older men. The FLOW study.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25307

Source
NTR

Health condition

LUTS, lower urinary tract symptoms, Pelvic floor dysfunction, Pelvic floor muscle training, Pelvic floor physiotherapy, alpha1-bockers, Symptoms of the lower urinary tract, slow urine stream, hesitation, urgency, nocturia and post void dribble, general practitioner, male patients, prostate incontinence.
Plasklachten, bekkenbodem, bekkenbodemspieren, fysiotherapie, bekkenbodemfysiotherapie, prostaat, man, incontinentie

Sponsors and support

Primary sponsor: Huisartsgeneeskunde UMC Groningen
Source(s) of monetary or material Support: Doelmatigheidsfonds van het UMC Groningen

Intervention

Outcome measures

Primary outcome

The primary outcome parameter is the change in lower urinary tract symptom score as measured with the International Prostate Symptom Scale (IPSS), a validated instrument to

assess symptoms and bother caused by LUTS.

Secondary outcome

Secondary outcome measures are the mean and maximum flow, as measured with free uroflowmetry, sexual functioning measured with the MLUTSsex questionnaire, quality of life, as measured with a quality of life question added to the IPSS (condition specific) and with the EQ-5D (generic quality of life) and global perception of improvement (GPI).

Study description

Background summary

Rationale:

The standard treatment in general practice for men with Lower Urinary Tract Symptoms, (LUTS) is with drugs from the class of alpha1-receptor blocking agents. Pelvic floor muscle training may be an alternative for drug treatment of LUTS: it is harmless and has no side effects. The effects of pelvic floor muscle training have not yet been studied in a randomized clinical trial, comparing this treatment with the standard treatment. The hypothesis is that pelvic floor muscle training has a favorable effect on the symptoms and improves the quality of life of men with LUTS in general practice more than the standard treatment with medication.

Objective:

The primary objective of the study is to study the effects of pelvic floor physiotherapy compared to treatment with ¦Á1-blocking agents in men with lower urinary tract symptoms.

The secondary objective is to study the effects of the two therapies on quality of life, the maximal and mean flow of urine, sexual functioning and to study the patient's global impression of improvement.

The pilot is necessary to study the feasibility of the recruitment procedure, the protocol for the pelvic floor physiotherapy and the measures of spread of the outcome parameters in a general practice population.

Study design:

The design of the study is an open label, randomized controlled trial. Patients will be

randomized 1:1 to a group receiving pelvic floor exercises or to a group receiving medication.

Study population:

Participants in the study will be older men (>50 years) with symptoms of LUTS, recruited by their general practitioner.

Intervention:

The patient group randomized to pelvic floor physiotherapy will be referred to a registered pelvic floor physiotherapist. In 6-9 sessions the patient will be educated on the role and function of the pelvic floor muscles in LUTS and on how to use this muscles to improve the micturition. The patient group randomized to the standard treatment with medication will be prescribed ¦Á1-receptor blocking agents (tamsulosin or alfuzosin) by his general practitioner. Duration of the two interventions is three months.

Main study parameters/endpoints:

The primary outcome parameter is the change in lower urinary tract symptom score as measured with the International Prostate Symptom Scale (IPSS).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

The risks of the study are minimal, as all investigations are non-invasive. The treatment in the medication group is non-experimental and the treatment in the pelvic floor exercise group is an accepted treatment for LUTS and has no side-effects.

The burden of the study for the participants consists of filling in questionnaires, keeping a two day bladder diary, undergoing a digital rectal examination and a measurement of the electrical activity of the pelvic floor muscles, urinating in a uroflowmeter and having a ultrasound examination of the lower abdomen to assess the post-void residual volume.

The results of the study may contribute to our knowledge about alleviating symptoms of the lower urinary tract in men. Pelvic floor physiotherapy may turn out to be an alternative for drug treatment.

Study objective

Pelvic floor muscle training has a favorable effect on the symptoms and improves the quality of life of men with LUTS in general practice more than the standard treatment with medication.

Study design

Included patients will be asked to complete the International Prostate Symptom Scale (IPSS) a validated instrument to assess symptoms and bother caused by LUTS, the MLUTSsex questionnaire [Rosen 1997], a bladder diary for two days, and the EQ-5D questionnaire and they will be interviewed by the student-researcher about urogenital problems, previous treatments, comorbidity and medication. After that, he will do an examination of the abdomen and a digital rectal examination to check the prostate and to assess the function of the pelvic floor muscles in a standardized way [Messelink, Dorey, Wyndaele]. He will perform a free uroflowmetry (a non invasive procedure) to measure the maximum and mean flow rate of the urine. After voiding, he will measure the residual volume by means of an abdominal ultrasound examination (Bladderscan® 6400). Urine will be examined with a dipstick and incubated for detection of infections using a dip slide (semi-quantitative measurement for bacteria).
Follow up measurements will be done three months after the start of the inclusion in the study. In case of waiting times for pelvic floor physiotherapy, the IPSS score will be measured again before the start of the treatment (questionnaire filled in by the patient), and subsequently three months after the start of this treatment.

Follow up measurements include questionnaires to be filled in by the patient (IPSS, MLUTSsex, EQ-5D, GPI), a bladder diary (to be filled in by the patient) and uroflowmetry including residual volume measurement by the student-researcher and measurement of the pelvic floor muscle function (digital assessment and EMG by the pelvic floor physiotherapist).

Intervention

Pelvic floor physiotherapy group:

In the physiotherapy group, patients will be referred to a specialized physiotherapist. This physiotherapist has done a 2 years training on pelvic floor problems, after his or her registration as a physiotherapist (master pelvic floor physiotherapy). All patients will be educated on pelvic floor function and dysfunction and on the relation of this dysfunction with their symptoms. The quality of the contractions and relaxations is described as absent, weak, normal or strong according to the classification of the International Continence Society and the Oxford pelvic floor muscle activity scale [Abrams, Dorey, Wyndaele]. The electrical activity of the pelvic floor muscles will be recorded, using an anal probe (ElectroMyoGraphy). Subsequently the patient will be treated by the physiotherapist, according to a protocol for LUTS.

The protocol for LUTS was developed using protocols published in studies on pelvic floor dysfunction [Dorey, MacDonald] and the one used in studies in the University Pelvic Floor Center Groningen [Messelink]. It was discussed with and approved by the participating

physiotherapists. During three months, the patients will visit the physiotherapist 6 times. The first 3 visits will take one hour each. The last 3 visits will take half an hour. During the first visit, patients will receive education on the anatomy of the lower urinary tract in men and on pelvic floor function and dysfunction. They will be informed about micturition behaviour and learn exercises on breathing and relaxation and also proprioceptive exercises . The physiotherapist will also examine the pelvic floor to evaluate contraction and relaxation of the pelvic floor muscles. Electromyography will be used to quantify the function of the pelvic floor muscles and to give feedback to the patient on the effect of the exercises (myofeedback training). The patient will be instructed to perform the pelvic floor exercises at home on a daily base. The cornerstone of the home exercises will consist of variations of contractions and relaxations of the pelvic floor muscles, twice a day during 15 minutes, but this may be adjusted as the therapy progresses, according to the needs of the individual patient. Myofeedback training will be offered, if necessary. During the last three sessions the physiotherapist will have a more motivational role: progress and adherence to the exercise program will be discussed and stimulated. Special attention will be given to the situations in daily life in which the patient is most bothered by his symptoms. (e.g. during the night or during social activities).

Medication group:

The research physician asks the patient¡¯s own general practitioner, to prescribe one of the two ¦Á1-blockers, mentioned in the guideline on ¡®Micturition problems in elderly men¡¯ from the Dutch College of General Practitioners: tamsulosin sustained-release capsule 0,4 mg once daily or alfuzosin 10 mg sustained-release tablet once daily [Wolters]. The choice of the ¦Á1-blocker is according to the preference of the GP. There is no evidence on significant differences in the effectiveness or side effects of these two ¦Á-blockers. ¦Á1-receptor blockers are registered for treating patients with LUTS. The main working mechanism is the relaxation of smooth muscle fibres in the bladder neck, the urethra and the prostate. This relaxation reduces the infravesical outflow resistance, resulting in an increase in the urine flow rate. The effect of ¦Á-blockers is independent of the size of the prostate. The effect has an early onset, within two weeks after the start of the treatment a patient will be aware of the improvement, if present. As long as the medication is taken the effect will remain. The adverse effects of tamsulosin and alfuzosin are similar. The most important ones being orthostatic hypotension and dizziness. Other side effects are nausea, diarrhea, headache, palpitations, rhinitis and abnormal ejaculation [NICE]. Contra-indications for the use of ¦Á-blockers are: anamnestic orthostatic hypotension, angio-edema or hepatic failure.

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Eligibility criteria

Inclusion criteria

1. Age 50 years or older;

2. LUTS symptoms, operationalised as an IPSS score of 8 and higher (range of the IPSS score is 0-35: ≤ 7 representsmild symptoms, 8-19 moderate symptoms and 20-35 severe symptoms) for more than 6 months;

3. Interpretable flow (minimal production of 100 ml of urine);

4. No treatment for LUTS in the preceding 6 months;

5. No urinary tract infection or neurological bladder disorders;

6. No urological malignancy or surgery of prostate, bladder, anus, pelvic floor;

7. No indwelling catheter or intermittent catheterization;

8. Being able to visit a pelvic floor physiotherapist or to fill in questionnaires in Dutch;

9. Informed consent.

Exclusion criteria

1. Terminal stage of disease (according to the general practitioner);

2. Psychiatric or cognitive disorders (according to the general practitioner);

3. Contra-indication for prescribing ¦Á1-blocking agents (according to the general practitioner and checked by the investigator);

4. Abnormal prostate gland as found by digital rectal examination.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-06-2011
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion

Date:	28-06-2011
Application type:	First submission

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
NTR-new	NL2813
NTR-old	NTR2954
Other	METc UMCG / ABR registratie nummer : 2011.113 / 36624.042.11;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A