

Pelvic floor exercises compared to medication in the treatment of older men with lower urinary tract symptoms (LUTS) in general practice. The FLOW study.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Urinary tract signs and symptoms
Study type	Interventional

Summary

ID

NL-OMON35725

Source

ToetsingOnline

Brief title

Lower urinary tract symptoms in older men: the FLOW study.

Condition

- Urinary tract signs and symptoms

Synonym

lower urinary tract symptoms in men, micturition problems

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: lower urinary tract symptoms, medication, older men, pelvic floor physiotherapy

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)

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

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.

Study objective

The primary objective of the study is to study the effects of pelvic floor physiotherapy compared to treatment with α 1-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.

A 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. The follow up period is 3 months.

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 α 1-receptor blocking agents (tamsulosin or alfuzosin) by his general practitioner. Duration of the two interventions is three months

Study burden and risks

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 has no side-effects.

The burden of the study for the participants consists of filling in questionnaires, keeping a 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 to be an alternative for drug treatment

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

Age 50 years or older

LUTS symptoms, operationalised as an IPSS score of 8 and higher

Interpretable flow (minimal production of 100 ml of urine)

No urological diseases or treatments other than LUTS

Exclusion criteria

Terminal stage of disease (according to the general practitioner)

Psychiatric or cognitive disorders (according to the general practitioner)

Contra-indication for prescribing α 1-blocking agents

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
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2011
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO	
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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

CCMO

ID

NL36624.042.11