

The role of the pelvic floor in Lower Urinary Tract Symptoms (LUTS) in men.

Published: 28-12-2006

Last updated: 10-05-2024

The main objective of this study is to assess the effectiveness of pelvic floor muscle therapy in comparison with α -blockers, in men with LUTS. The second objective is the validation of the questionnaire (MPFS) in this group of patients

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

Summary

ID

NL-OMON30668

Source

ToetsingOnline

Brief title

Male pelvic floor and LUTS

Condition

- Urinary tract signs and symptoms

Synonym

LUTS, 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: LUTS, men, pelvic floor

Outcome measures

Primary outcome

The main endpoint of this study is the improvement in symptoms as measured by uroflowmetrie

Secondary outcome

The secondary endpoint of this study is the improvement in International Prostate Symptom Score (IPSS), micturition diary and EMG of the pelvic floor.

Study description

Background summary

Male patients are referred to the urologist when they report Lower Urinary Tract Symptoms (LUTS). In daily practice most patients with LUTS will be treated with an α -blocker. This treatment has been used for many years and proven to be effective. During the last 5 years the role of the pelvic floor muscles (PFM) in LUTS has been suggested to be of important value. When the pelvic floor muscles are overactive, they will contract when they should relax. When this is done during voiding the patient will experience LUTS, like slow stream, hesitation, nocturia and post void dribble. So far there are no publications on the effect of Pelvic Floor Muscle Therapy (PFMT) in this group of patients. In this study we investigate the effectiveness of PFMT compared to pharmacological treatment with α -blockers, being the gold standard. The results are evaluated using uroflowmetrie, a micturition diary, the International Prostate Symptom Score (IPSS) and an EMG of the pelvic floor. The Male Pelvic Floor Symptomscore (MPFS) is a questionnaire that will be validated in this study.

Study objective

The main objective of this study is to assess the effectiveness of pelvic floor muscle therapy in comparison with α -blockers, in men with LUTS. The second objective is the validation of the questionnaire (MPFS) in this

group of patients

Study design

A multicenter, prospective, randomised controlled intervention study, using medication and physiotherapy.

Intervention

One group receives an α -blocker once daily for 4 months. The other group receives physiotherapy of the pelvic floor muscles, for 4 months

Study burden and risks

Patients in both groups have to perform a uroflowmetrie 2 times. A uroflowmetrie means voiding on a normal toilet, in private. Inside the toilet is a measuring device. An EMG of the pelvic floor muscles is performed 2 times. The EMG is done with an anal probe. Patients also have to fill out the IPSS, a micturition diary and the MPFS 2 times. Except for the MPFS these are all regular diagnostic procedures. All patients receive a form of active treatment.

Contacts

Public

Universitair Medisch Centrum Groningen

Postbus 30001
9700 RB Groningen
Nederland

Scientific

Universitair Medisch Centrum Groningen

Postbus 30001
9700 RB Groningen
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Slow urinary stream, hesitation, nocturia

Exclusion criteria

Urinary tract infection, neurogenic bladder, catheter

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:	Pending
Start date (anticipated):	01-02-2007
Enrollment:	190
Type:	Anticipated

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	ID
CCMO	NL15270.042.06