Electromyographic feedback in the treatment of the pelvic floor in Lower Urinary Tract Symptoms (LUTS) in men.

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The main objective of this study is to assess the additive effect of EMG-feedback in the treatment of LUTS in men.

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

Summary

ID

NL-OMON32050

Source
ToetsingOnline

Brief title
Biofeedback in Men with 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: industrie,Pelvitec

Intervention

Keyword: feedback, LUTS, men, pelvic floor

Outcome measures

Primary outcome

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

Secondary outcome

The secondary endpoint of this study is the improvement in International Prostate Symptom Score (IPSS), Male Pelvic Floor Symptomscore, the micturition diary and the 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 *-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 pilot studies the effect seems to be fairly good. Pelvic floor muscle therapy has different modalities. One of them is the EMG-feedback, which is often used in treating male patients with pelvic floor muscle dysfunction. The additive effect however has never been proven.

Study objective

The main objective of this study is to assess the additive effect of EMG-feedback in the treatment of LUTS in men.

Study design

A prospective randomised controlled intervention study. Patients are randomly assigned to two groups: pelvic floor physiotherapy alone or in combination with EMG-feedback.

Intervention

Both groups receive physiotherapy of the pelvic floor muscles, in one of the two groups EMG-feedback is added in the other it is not.

Study burden and risks

Patients in both groups have to perform a uroflowmetrie 2 times. A uroflowmetry 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:	Recruitment stopped
Start date (anticipated):	22-07-2019
Enrollment:	186
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	ID
CCMO	NL22053.042.08