Bladder training with or without PTNS(Posterior Tibial Nerve Stimulation) in the treatment of Overactive Bladder

Published: 27-04-2009
Last updated: 18-07-2024

The main objective of this study will be to assess whether an additive stimulation of the posterior tibial nerve (PTNS) in combination with bladder training has a significant reduction in frequency of micturition in patients with overactive bladder...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bladder and bladder neck disorders (excl calculi)
Study type	Interventional

Summary

ID

NL-OMON32999

Source
ToetsingOnline

Brief title
Bladder training and PTNS in the treatment of overactive bladder

Condition

- Bladder and bladder neck disorders (excl calculi)

Synonym
urge incontinence

Research involving
Human

Sponsors and support

Primary sponsor: Afstudeeronderzoek Evidence Based Medicine UvA
Source(s) of monetary or material Support: geen financiering

Intervention

Keyword: elektro-acupuncture, overactive bladder, PTNS(posterior tibial nerve stimulation)

Outcome measures

Primary outcome

* The primary outcome is the percentage of patients with a 70% improvement

in the ICIQ-Sf total score.

Secondary outcome

* Secondary outcomes to be measured:

* Micturition frequency at 6-12 wks/ daytime/nightime

* Reduction in UUI (Urge Urinary Incontinence) episodes/pwk

Study description

Background summary

Overactive Bladder is a disabling condition with a great impact on Quality of Life. With an overall prevalence rate of 11,8% it affects millions of people around the world. In addition to the non-invasive conservative treatment options like medication, bladder training and/or pelvic muscle floor training a newly intervention is explored in recent years. This peripheral neuromodulation technique is developed from old Chinese acupuncture knowledge, whereas the posterior tibial nerve is stimulated at a location of an acupuncture point three fingerbreadths above the inner ankle. The main group of patients receiving this intervention are those who are refractory to conservative treatment. In this study we*re trying to investigate whether it is clinically relevant to bring it forward in the decision tree. The main objective of this study will be to assess whether an additive stimulation of the posterior tibial nerve (PTNS) in combination with bladder training has a significant reduction in frequency of micturition, urge urinary incontinence episodes and quality of life, measured by the ICIQ-sf in patients with overactive bladder than bladder training alone

Study objective

The main objective of this study will be to assess whether an additive

stimulation of the posterior tibial nerve (PTNS) in combination with bladder training has a significant reduction in frequency of micturition in patients with overactive bladder than bladder training alone.

Study design

A prospective Randomized Clinical Trial
two arms:

Bladder training
Bladder training and PTNS

Intervention

Bladder training and PTNS

Study burden and risks

The burden could be the extra time to be invested.

Risks are minimal: there is a little possibility of minor bleedings.

Contacts

Public
Afstudeeronderzoek Evidence Based Medicine UvA

atalantahof 16
3544VD utrecht
Nederland
Scientific
Afstudeeronderzoek Evidence Based Medicine UvA

atalantahof 16
3544VD utrecht
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All patients diagnosed with OAB syndrome will be included.
Criteria for diagnosis are as follow:
* Urgency and frequency: more than 8 voids per 24 hours and the sudden urge to void can hardly be suppressed.
* Urge incontinence: urgency leading to urinary leakage occurring at least three times weekly
* willingness to fill up a daily bladder diary.
* age > 18yrs

Exclusion criteria

* Symptoms existing for less than 6 months
* Pregnancy.
* Active urinary tract or recurrent urinary tract infection
* Severe cardiopulmonary disease
* Diabetes with peripheral nerve involvement
* Neurological disorders
* flowmetrie < 15mm/sec

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):	01-06-2009
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	27-04-2009
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	10-12-2009
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL26931.098.09