Blaastraining en PTNS bij overactieve blaas.

No registrations found.

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

Summary

ID

NL-OMON25864

Source
Nationaal Trial Register

Brief title
PTOAB study

Health condition

Overactive Bladder.

Urge incontinence/ aandrang incontinentie

Sponsors and support

Primary sponsor: NVA Nederlandse Vereniging voor Acupunctuur
NVA (Nederlandse Vereniging voor Acupunctuur)
Van Persijnstraat 17
3811 LS Amersfoort
telnr: 0334654062
Source(s) of monetary or material Support: NVA Dutch Organisation of Acupuncture

Intervention

Outcome measures

Primary outcome

ICIQ-ui-sf scores: Percentage of 70% improvement on the ICIQ-ui-sf scores.

H0 hypothesis: There will be no difference in the ICIQ-sf scores of the two arms.

Scores ranging from 0-21.

Secondary outcome

1. Incontinence episodes per week;

2. Frequency of micturition per 24h.

Study description

Background summary

In the guidelines of Overactive Bladder , PTNS is prescribed when all other treatments have failed. In the trial we want to investigate the efectiveness when given primarily. And particularly when it is given in combination with the now already given bladder training.

Study objective

An combination therapy of Bladder Training with PTNS will significantly reduce the symptoms of overactive bladder in comparison with a Bladder Training program alone

Study design

1. Baseline;

2. 6 weeks;

3. 12 weeks.

Intervention

1. PTNS (Posterior tibial nerve stimulation);

2. Bladder training.

Two arms:

1. Bladder training;

2. Bladder training and PTNS.

Contacts

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Eligibility criteria

Inclusion criteria

All patients diagnosed with OAB syndrome will be included.
Criteria for diagnosis are as follow:

1. Urgency and frequency: more than 8 voids per 24 hours and the sudden urge to void can hardly be suppressed;

2. Urge incontinence: urgency leading to urinary leakage occurring at least three times weekly;

3. Age > 18yrs.

Exclusion criteria

1. Symptoms existing for less than 6 months;

2. Pregnancy;

3. Active urinary tract or recurrent urinary tract infection;

4. Severe cardiopulmonary disease;

5. Diabetes with peripheral nerve involvement;

6. Neurological disorders;

7. Flowmetrie < 15mm/sec;

8. Had already treatment for overactive bladder.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2009
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	26-01-2010
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	NL2075
NTR-old	NTR2192
Other	METC : 09030
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A