Percutaneous tibial nerve stimulation of fecal incontinence: a multi center, randomized, placebo controlled study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON33182

Source
ToetsingOnline

Brief title
PTNS in the treatment of FI

Condition

- Other condition

Synonym
Fecal incontinence

Health condition

Fecale incontinentie

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,Uroplasty B.V.

Intervention

Keyword: fecal incontinence, nerve stimulation, tibial nerve

Outcome measures

Primary outcome

The percentage of patients experiencing a * 50% decrease in incontinence

episodes from baseline after 9 weeks of treatment.

Secondary outcome

Mean change in the Cleveland Clinic Florida Fecal Incontinence Score (CCF-FI

Score)

Mean change in Quality of Life scores in validated QoL questionnaires (SF-36,

Digestive Health Status Instrument (DHSI), and Fecal Incontinence Quality of

life)

Subject*s and Physician*s Global Impression

Study description

Background summary

Fecal incontinence is a complex problem. The social consequences of this problem result in a lower quality of life. The exact prevalence of FI is unknown, literature reports vary from 13-19%. There are variable treatment options depending on the patient and the etiology of the FI. Dietary manipulation, pharmacological intervention, pelvic floor physiotherapy, as well

as surgical interventions are currently used to treat FI.

A promising current treatment is Percutaneous Tibial Nerve Stimulation (PTNS). The nerves in the spine that control bowel function also have branches which go to the ankle. Stimulating these nerves in the ankle has shown to be an effective treatment for FI in the short-term. The treatment has been shown to be safe and well tolerated by subjects with almost no morbidity in prior urology trials.

Study objective

The objective of this study is to show that the results of PTNS are based on the treatment of electrical stimulation and not on a placebo effect with a sham treatment.

Study design

This study is a multicenter, single-blinded, randomized, placebo-controlled trial.
Physicians will recruit and inform prospective subjects in the outpatient clinic about this study. Subjects who are interested in participating in this study will be provided informed consent at a minimum of one week prior to study treatment.
The study will be performed in a multicenter setting including, but not limited to, Maastricht University Medical Center in the Netherlands as well as other sites such as La Sapienza University hospital in Rome Italy, and the CCDE-IMAD-Hôtel-Dieu in Nantes France.

Study duration will consist of 9 weeks for the treatment group and the sham group. During the first 6 weeks, both groups will receive treatment or sham sessions twice a week. After six weeks, treatment outcomes will be assessed by the CCF-FI score, IBS, QoL questionnaires and a Global Impression of the condition by the Subject and Physician. Subjects will also initiate a 3-week bowel habit diary. During the following three weeks (weeks 7-9) the treatment or sham sessions will be continued for once a week. After 9 weeks, at the completion of the bowel habit diary, the outcomes will be assessed again with the CCF-FI score, IBS and QoL questionnaires and a Global Impression of the condition by the Subject and Physician. All subjects will be unblinded at the conclusion of 9 weeks. Those who were randomized to the sham treatment will be offered the same PTNS treatments as the treatment group twice a week for 6 weeks followed by three weeks of weekly treatment. If sham treatment was successful patients will still be offered this PTNS treatment to provide possible additional effect. This continued treatment will be at the patients discretion. Analysis of this group will be at 15 and 18 weeks as compared to their own parameters at baseline and after sham treatment.
Maintenance treatment schedule will start after week 6 for both of the

treatment groups and after week 15 for the patients originally in the sham group who at their own discretion decided to continue PTNS treatment. Week 7-9 of the protocol are in fact part of the maintenance treatment and are blinded in the original format.
Follow-up will be evaluated at six and twelve months using a bowel habit diary, CCF-FI score, IBS, QoL questionnaires and a Global Impression of the condition by the Subject and Physician.

Intervention

The Urgent®PC device (Uroplasty, Geleen, The Netherlands) used to deliver PTNS is a combination of lead set and stimulator components, including a 34-gauge needle electrode, surface electrode, lead wire and hand-held pulse generator. This device is CE marked and indicated for treatment of Fecal Incontinence, urinary frequency, urinary urgency and urge incontinence. The low voltage stimulator powered by a 9-volt battery has an adjustable current setting ranging from 0 to 9 mA, a fixed pulse width of 200 microseconds and a frequency of 20 Hz. The device produces an electrical impulse that accesses the sacral nerve plexus via the tibial nerve.
The needle is inserted in both groups at the same location near the medial malleolus (ankle). The location is about 5 cm cephalad of the medial malleolus and about 2 cm posterior to the tibia. The needle is then advanced towards the nerve. The needle will then be connected to the stimulator and correct placement will be confirmed by increasing the stimulator setting until toe flexion and/or sole twinkling are observed. For therapy in the treatment group, the stimulator will be turned on for 30 minutes. In the sham group the stimulator will be turned back to 0 mA and then turned on for 30 minutes to activate the timer.

Study burden and risks

Prior studies revealed some adverse events that can occur. The most common adverse event reported is bleeding at the needle entry site and numbness in the treated leg after treatment persisting for several hours. There is a small risk of infection at the needle site. These risks are low and if they occur they are mild. No irreversible, serious adverse events have been reported with PTNS. The benefit of this study will be an increase understanding of the efficacy that PTNS provides in the treatment of FI. With this evidence, this treatment may become incorporated into everyday practice.

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

- Written informed consent
- Must be at least 18 years of age
- Fecal incontinence with solid or liquid stool causing disruption of the subject*s lifestyle
- Psychological stability as determined by the treating physician
- Willingness to commit to a rigid follow-up schedule and comply with the investigational plan
- Failed conservative therapy
- During treatment the patient exhibits an adequate motor and/or sensory response (flexion of toe and/or twinkling sensation)
- Is able to read and write

Exclusion criteria

- Major internal and/or external sphincter defect (defined as >33% of the anal circumference)
- Fecal impaction
- Pacemaker, implanted defibrillator
- Pregnancy or intention to become pregnant
- Neurogenic or congenital disorders resulting in FI

- Inability to travel to the clinic twice a week

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-02-2010
Enrollment:	32
Type:	Actual

Ethics review

Approved WMO

Date:	02-11-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 21495
Source: NTR
Title:

In other registers

Register	ID
ClinicalTrials.gov	NCT00974909
CCMO	NL28955.068.09
OMON	NL-OMON21495