Intermitterende sacrale neuromodulatie bij idiopathische overactieve blaas.

No registrations found.

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

Summary

ID

NL-OMON23224

Source
NTR

Brief title
Intermittent sacral neuromodulation

Health condition

Overactive bladder, sacral neuromodulation

Sponsors and support

Primary sponsor: Erasmus Medical Center Rotterdam, Department Urology.
Source(s) of monetary or material Support: Stichting Theia
SUWO

Intervention

Outcome measures

Primary outcome

Incontinence episodes per day compared to baseline, derived from voiding diaries.

Secondary outcome

Derived from voiding diaries

- Urinary frequency per 24 hours

- Number of pads used

- Average volume per voiding.

Change from baseline to intermittent stimulation

Difference between intermittent and continuous stimulation.

Standard scores from questionnaires (IIQ-7, UDI-6, PFDI-20, PFIQ-7, PISQ, EuroQOL-5, FICI, FIQL)
Change from baseline to intermittent stimulation.
Difference between intermittent and continuous stimulation.

Study description

Background summary

Overactive bladder (OAB) is a condition that is difficult to treat. Due to the increasing age in the population, it is also a condition that increases in incidence and prevalence in coming years. Neuromodulation has been proven to be a successful treatment for OAB. One of the main forms of neuromodulation is sacral neuromodulation (SNM). The reason why this method is used to a limited degree include the total costs and its invasiveness. Other forms of neuromodulation use intermittent stimulation with a proven reduction of symptoms of OAB. Several studies have shown the effectiveness of SNM using continuous stimulation. However, there has been no report of intermittent stimulation using SNM. Given the results of these alternative forms of neuromodulation it appears this intermittent stimulation must have a similar effect for SNM. This will improve the accessibility of SNM in two areas; significant cost saving and a reduction in invasiveness because of a reduction in the total amount of battery changes that patients need to undergo.

Patients will have to visit the hospital four times. This will be combined with a regular outpatient appointment if possible. An increase in symptoms of overactive bladder may occur during the study period. The service life of the battery of the neurostimulator may be elongated which will result in a reduction of the total amount of battery substitutions for this group of patients, given that intermittent neurostimulation has a minimal improvement of 50% of the symptoms of OAB compared to baseline.

Study objective

To elongate the service life of the implantable neurostimulator while achieving a minimal improvement of 50% of the symptoms of overactive bladder compared to baseline.

Study design

Weeks 1,2,3,4,5,8,12,16.

Intervention

In all patients the implantable neurostimulator will be automatically turned off for 18 hours a day.

Contacts

Public

L.A. Hoen, 't
Dept. Urology, room Na-17
Erasmus MC
Wytemaweg 80
Rotterdam 3015 CN
The Netherlands
010 - 703 65 59
Scientific

L.A. Hoen, 't
Dept. Urology, room Na-17
Erasmus MC
Wytemaweg 80
Rotterdam 3015 CN
The Netherlands
010 - 703 65 59

Eligibility criteria

Inclusion criteria

Patients who:

• have given written informed consent

• have sufficient knowledge of the Dutch language to understand the informed consent form and to complete the questionnaires

• are female and are at least 18 years of age

• have had subjective successful treatment for at least 6 months through sacral neuromodulation using InterStim for OAB

• have had at least three months of anticholinergic treatment without result or who had to stop anticholinergic treatment because of adverse side effects before implantation of the neuromodulator

• currently do not use anticholinergic or other medical treatment for idiopathic OAB

• have had their last intravesical Botox treatment at least 12 months ago

Exclusion criteria

Patients who:

• have a neuropathic bladder

• have a symptomatic urinary tract infection

• have an indwelling catheter or who apply clean intermittent catheterization

• have an implantable neurostimulator of which the estimated service life of the battery is less than 1 year at the moment of inclusion in the study

• have had radiation therapy of the pelvis

• have had bladder cancer

Study design

Design

Study type:	Interventional
Intervention model:	Other

Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2014
Enrollment:	16
Type:	Anticipated

Ethics review

Positive opinion

Date:	08-09-2014
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	NL4622
NTR-old	NTR4773
Other	NL45630.078.13 : MEC-2013-351

Study results