Intermittent sacral neuromodulation for treatment of idiopathic overactive bladder in women

Published: 30-04-2014
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The aim is to elongate the service life of the implantable neurostimulator while achieving a minimal improvement of 50% of the symptoms of OAB.

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

Summary

ID

NL-OMON40167

Source
ToetsingOnline

Brief title
Intermittent sacral neuromodulation

Condition

- Bladder and bladder neck disorders (excl calculi)

Synonym
overactive bladder, urinary incontinence

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: SUWO (Stichting Urologisch Wetenschappelijk Onderzoek) en Theia

Intervention

Keyword: elongation service life neurostimulator, intermittent stimulation, overactive bladder in women, sacral neuromodulation

Outcome measures

Primary outcome

The primary endpoint will be incontinence episodes per day compared to

baseline.

Secondary outcome

- Urinary frequency per 24 hours

- Number of pads used

- Average volume per voiding

This will be derived from the voiding diaries. The change from baseline to

intermittent stimulation will be determined. The difference between

intermittent and continuous stimulation will also be determined, for

incontinence episodes per day as well.

Standard scores derived from the 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

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.

Study objective

The aim is to elongate the service life of the implantable neurostimulator while achieving a minimal improvement of 50% of the symptoms of OAB.

Study design

A prospective cohort study in a singel-center setting.

Intervention

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

Study burden and risks

OAB symptoms may increase during the wash out period and the intermittent stimulation period. During the study patients will not be exposed to risks other than known for the standard use of the implantable neurostimulator. Four hospital visits are required for participating patients. Study visits will be combined with regular outpatient visits if possible.

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
- sufficient knowledge of the Dutch language to understand the informed consent form and to complete the questionnaires
- female at least 18 years of age
- subjective successful treatment for at least 6 months through sacral neuromodulation using InterStim for OAB
- at least three months of anticholinergic treatment without result or had to stop anticholinergic treatment because of adverse side effects before implantation of the neuromodulator
- currently not using anticholinergic or other medical treatment for idiopathic OAB
- last intravesical Botox treatment at least 12 months ago

Exclusion criteria

- neuropathic bladder
- symptomatic urinary tract infection
- indwelling catheter or clean intermittent catheterization
- implantable neurostimulator of which the estimated service life of the battery is less than 1 year at the moment of inclusion in the study
- radiation therapy of the pelvis
- (previous) bladder cancer

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-07-2014
Enrollment:	16
Type:	Actual

Ethics review

Approved WMO Date:	30-04-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL45630.078.13