Intermitterende sacrale neuromodulatie bij idiopathische overactieve blaas.

Gepubliceerd: 08-09-2014 Laatst bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23224

Bron
NTR

Verkorte titel
Intermittent sacral neuromodulation

Aandoening

Overactive bladder, sacral neuromodulation

Ondersteuning

Primaire sponsor: Erasmus Medical Center Rotterdam, Department Urology.
Overige ondersteuning: Stichting Theia
SUWO

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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

Wetenschappelijk

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

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-06-2014
Aantal proefpersonen:	16
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	08-09-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4622
NTR-old	NTR4773
Ander register	NL45630.078.13 : MEC-2013-351

Resultaten