Onderzoek naar de optimale duur van de testperiode van behandeling met sacrale neuromodulatie.

Gepubliceerd: 12-11-2013 Laatst bijgewerkt: 18-08-2022

The experience in our clinic during test stimulation period is that for responders it takes up to one week to achieve maximal effect, after the system is turned ‘on’. On the other hand we notice that after turning the neuromodulation system ‘off’,...

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

Samenvatting

ID

NL-OMON25907

Bron
Nationaal Trial Register

Verkorte titel
“Wash in – wash out”

Aandoening

overactive bladder (OAB)
non-obstructive urinary retention (NOR)
sacral neuromodulation (SNM)

overactieve blaas
niet-obstructieve urine retentie
sacrale neuromodulatie

Ondersteuning

Primaire sponsor: Department of Urology,
dr. van Koeveringe, urologist
Maastricht Universitair Medisch Centrum
Overige ondersteuning: Stichting wamU

(wetenschappelijke activiteiten maastrichtse urologie)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The transition point between no effect and time of onset is determined by assessing when certain complaints parameters are reduced by 50% compared to baseline per 24 hours. Vice versa (50% increase) for offset of effect. Onset and offset of effect will be assessed in days.

Toelichting onderzoek

Achtergrond van het onderzoek

Sacral neuromodulation is a minimally invasive secondary treatment for overactive bladder syndrome (OAB) or for non-obstructive
urinary retention (NOR), when refractory to conservative treatment. Success rates range from 70 to 80%, and good long-term
results are reported. The working mechanism of SNM is not completely understood, and the only prognostic factor for good
response to this treatment is a successful test stimulation period. There is no consensus on the duration of this test stimulation
period. The experience in our clinic during test stimulation period is that for responders it takes up to one week to achieve maximal
effect, after the system is turned ‘on’. On the other hand we notice that after turning the neuromodulation system ‘off’, it will take a
few hours for symptoms to return to the baseline situation. The fact is: no information concerning the so called “time of onset” and
“time of offset” (or popular called: wash-in / wash-out) of sacral neuromodulation is available in current literature.

The main objective is to evaluate the average time span within which “time of onset” and “time of offset” occurs in patients with
overactive bladder syndrome or non-obstructive urinary retention who respond to SNM.

Doel van het onderzoek

The experience in our clinic during test stimulation period is that for responders it takes up to one week to achieve maximal effect, after the system is turned ‘on’. On the other hand we notice that after turning the neuromodulation system ‘off’, it will take at least a few hours for symptoms to return to the baseline situation.

Onderzoeksopzet

During the course of 5 to 6 months there are four measuring moments.

Onderzoeksproduct en/of interventie

After inclusion and informed consent, patients will fill out a baseline voiding diary throughout seven days. The 28 day test stimulation period starts on the day of the first tined lead procedure. On day 14 the stimulation is turned ‘off’, on day 22 the stimulation is turned ‘on’ again. During the study period patients should fill out an elaborate voiding diary for in total 28 (non-consecutive) days.

Contactpersonen

Publiek

Maastricht Universitair Medisch Centrum
Afdeling Urologie | P. Debyelaan 25 | postbus 5800
J. Drossaerts
Maastricht 6202 AZ
The Netherlands
043-3877255

Wetenschappelijk

Maastricht Universitair Medisch Centrum
Afdeling Urologie | P. Debyelaan 25 | postbus 5800
J. Drossaerts
Maastricht 6202 AZ
The Netherlands
043-3877255

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria: Patients should have been diagnosed with overactive bladder syndrome or non-obstructive urinary retention and should be put on the waiting list for scheduling treatment

with sacral neuromodulation.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study: a) patients receiving neurological or psychiatric medication without being diagnosed with a neurological or psychiatric
disease; b) patients who have been treated by means of bladder wall botuline toxine injections in the past twelve months; c) patients with evident subsequent complains of bladder pain syndrome or other pelvic pain.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-12-2013
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	12-11-2013
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	NL4016
NTR-old	NTR4259
Ander register	Dossiernummer NL44879.068.13 : ABR Nummer 44879
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A