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

No registrations found.

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

Summary

ID

NL-OMON25907

Source
Nationaal Trial Register

Brief title
“Wash in – wash out”

Health condition

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

overactieve blaas
niet-obstructieve urine retentie
sacrale neuromodulatie

Sponsors and support

Primary sponsor: Department of Urology,
dr. van Koeveringe, urologist
Maastricht Universitair Medisch Centrum
Source(s) of monetary or material Support: Stichting wamU
(wetenschappelijke activiteiten maastrichtse urologie)

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Not applicable.

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2013
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

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

Study results

Summary results
N/A