Time of onset and time of offset of sacral neuromodulation effect.

Published: 02-01-2014
Last updated: 18-07-2024

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.

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

Summary

ID

NL-OMON50444

Source
ToetsingOnline

Brief title
Wash in - wash out

Condition

- Bladder and bladder neck disorders (excl calculi)

Synonym
Non-obstructive urinary retention (NOR), Overactive bladder (OAB)

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Stichting wamU (wetenschappelijke activiteiten maastrichtse Urologie)

Intervention

Keyword: non-obstructive urinary retention, overactive bladder, sacral neuromodulation

Outcome measures

Primary outcome

The transition point between no effect and time of onset is determined by

assessing when symptoms are reduced by 50% compared to baseline. Vice versa for

time of offset. Time of on set and offset will be assessed in days (24 hours).

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.

Study objective

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 design

The study is designed as a prospective patient series.

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 dairy for in total 28 (non-consecutive) days.

Study burden and risks

Patients will have to fill out micturition lists for a longer time period than during regular sacral neuromodulation treatment. Within the test stimulation period the included patients have to turn the stimulation *off** during 7 days, whereas in regular patients stimulation is *on* during the full 28 days of the test period. The voiding dairies should be filled out during four time periods, within a time span of six months. There are no additional risks, that we know of, associated with participation.

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

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

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-03-2014
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	Sacral neuromodulation system
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	02-01-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	11-07-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL44879.068.13