Optimal Stimulation Rates in Sacral Neuromodulation Therapy

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To determine whether rate change is feasible and has a positive influence on the effect of SNS on the symptoms measured with voiding diaries.To investigate whether there are differences between optimal stimulation settings between patients with SNS...

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

Summary

ID

NL-OMON31616

Source
ToetsingOnline

Brief title
Rate study

Condition

- Bladder and bladder neck disorders (excl calculi)

Synonym
incontinence, overactive bladder, urinary retention

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: rate-frequency, sacral neuromodulation, settings

Outcome measures

Primary outcome

Improvement in voiding diaries results between the *standard* frequency (10 Hz) and pulsewidth (210µs) and new settings. Improvement is measured by computer assisted comparison of voiding diaries taken with the *standard* settings and with the new settings and is reflected in percentage improvement achieved

Secondary outcome

* Patient toleration of rate changes.

* Difference between optimal settings between patients with either urge symptoms or retention symptoms.

Study description

Background summary

Patients with refractory symptoms of urge-incontinence, urgency-frequency and urinary retention without obstruction who do not respond to conservative treatment like medication and/or physical therapy, can get symptom relief by sacral nerve stimulation (SNS). It is postulated that the mechanism of neuromodulation is based upon restoring the correct balance between excitatory and inhibitory impulses from and to the pelvic organs at a sacral and supra-sacral level via pulses through the afferent small myelinated Aδ and unmyelinated C nerve fibers.
Stimulation is achieved using an electrode, which is implanted unilaterally at the site of the S3 nerve root and connected to a stimulator implanted at the buttock or abdomen. The implantable pulse generator (IPG) has a variety of settings. The pulse rate (PR) can be set between 2.1 and 130 Hz and the pulse width (PW) between 60 and 450 ms. The amplitude can be changed from 0.05 to 10,55 V. Patients who are implanted with a neuromodulation system receive an external programmer, which is used to change the amplitude of the stimulation current.

It is customary in most clinics where SNS is applied to set the PR of the IPG at 10 Hz and the PW at 210 ms. These parameters have been advised in the beginning of SNS therapy development. The choice of these parameters is based on animal experiments. Studies in animal models suggests that PR of more than 50 Hz might be detrimental to the stimulated nerve because of the occurrence of early axonal degeneration.

Study objective

To determine whether rate change is feasible and has a positive influence on the effect of SNS on the symptoms measured with voiding diaries.
To investigate whether there are differences between optimal stimulation settings between patients with SNS for urge symptoms or for retention symptoms.

Study design

study with single subject design

Intervention

Change the pulse rate of the implanted neurostimulator in patients with implanted neuromodulation system. Frequencies will be changed to 5.2Hz, 10Hz, 25Hz and 40Hz, each frequency will be used during one week.

Study burden and risks

The burden for these patients is minimal. Although it will cost the patient some time to fill out the questionnaire and diaries and travel to and from Maastricht. Furthermore, there is a possibility that the patient will experience some discomfort because it is possible that certain frequencies will have a decreased effectiveness.
The frequencies that has been chosen in this study are well within the safety limits that are determined by animal experiments. Therefore we do not expect any adverse effects from the stimulation on the patient*s sacral nerves. However, there are clinical reports of a small amount of patients who find stimulation with a frequency below 10Hz uncomfortable. If patients have discomfort of the stimulation parameter settings during the study they are advised to contact their urologist and to turn their IPG off.

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

Patients with Sacral Neuromodulation therapy for complaints of urge incontinence, urgency frequency, hypocontractile detrusor or obstruction due to urethral sphincter overactivity.

Exclusion criteria

Patients with Sacral Neuromodulation Therapy for other reasons than mentioned in the inclusion criteria

Study design

Design

Study type: Interventional

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-09-2008
Enrollment:	54
Type:	Actual

Ethics review

Approved WMO

Date:	10-12-2007
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	18-07-2008
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	NL17682.068.07
Other	NTR-1131