Optimal Stimulation Rates in Sacral Neuromodulation Therapy.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26922

Source
NTR

Brief title
N/A

Health condition

Urinary Frequency/Urge, Urge incontinence and Non obstructive Urinary Retention.

Sponsors and support

Source(s) of monetary or material Support: fund=initiator=sponsor

Intervention

Outcome measures

Primary outcome

1. 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

1. Patient toleration of rate changes;

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

Study description

Background summary

History at time of registration

Planned startdate

1-Jan-2008

Planned closingdate

1-Jul-2008

Target number of participants n=10

Study objective

In this single subject study we would like to determine whether parameter optimizing is feasible. Furthermore we want to investigate whether patients with urge symptoms have optimal benefit from different parameters than patients with non-obstructive urinary retention.

Study design

Weekly controls.

Intervention

Current trial information

In this study patients with sacral neuromodulation therapy are included. We will start with changing the pulse rate to 3 other different Hz (5.2 - 25- 40) and once to the usual 10 Hz (as control).

History at time of registration

In this study patients are included the moment we know they are eligible for the second stage TLP. After one week we will start with changing the pulse rate to 3 other different Hz (5.2 - 25- 40) and once to the usual 10 Hz (as control). The order of the pulse rate is different per person. Each change of the pulse rate will last one week. In this week patients are asked to keep a voiding diary for three days and fill in a questionnaire.

Contacts

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Eligibility criteria

Inclusion criteria

Current trial information

1. Patients who signed the informed consent.

2. Patients (male and female), aged between 18-80 years, with SNM therapy for complaints of urge incontinence or urgency frequency.

3. Patients (male and female), aged between 18-80 years, with SNM therapy for complaints of urinary retention or voiding dysfunction, such as hesitancy or intermittence, that are due to an hypocontractile detrusor or obstruction due to urethral sphincter overactivity.

4. A suboptimal result with the treatment. For patients with incontinence this means that they are not completely dry. For patients with retention this means that they still have to use a catheter to void.

History at time of registration

1. Patients (male and female), aged between 18-60 years, with urge incontinence or urgency frequency, with overactive detrusor contractions on cystometry, who have been successfully tested for treatment with SNS. Successful treatment will be defined as > 50% improvement in the relevant voiding symptoms and will be measured by comparison of a voiding diary during the test before implant with the voiding diary before implant;

2. Patients (male and female), aged between 18-60 years, with urinary retention or voiding dysfunction, such as hesitancy or intermittence, that are due to an hypocontractile detrusor or obstruction due to urethral sphincter overactivity, demonstrated on cystometry , who have been successfully tested for treatment with SNS. Successful treatment will be defined as > 50% improvement in the relevant voiding symptoms and will be measured by comparison of a voiding diary during the test before implant with the voiding diary before implant.

Exclusion criteria

Current trial information

1. People who have SNM therapy for other reasons which is not mentioned in the such as abdominal pain.

2. People of which their battery needs to be replaced by a new one, due to low battery life.

History at time of registration

Conditions which preclude patient suitability for SNS therapy:

1. Patients with current psychiatric disorders;

2. Current or plans of pregnancy;

3. Neurologic voiding disorders; including DM (severe or uncontrolled diabetes; or diabetes with peripheral nerve involvement), spinal cord injury, MS;

4. Reiter’s syndrome;

5. Concomitant medical conditions that would limit the success of the procedure such as: active degenerative disc disease, spinal cord injury< 6 months old, bleeding complications, CVA< 6 months old etc;

6. Extraurethral incontinence;

7. Pelvic pain of uncertain etiology that is not associated with a voiding dysfunction or where

pelvic pain is the primary complaint/ diagnosis;

8. Anatomic obstructive voiding disorders;

9. Current urinary tract infection;

10. Malignancy of urinary tract;

11. Severe grade III/IV pelvic prolapse, cystocele, urethrocele, enterocele;

12. Proven interstitial cystitis or clinical symptoms of interstitial cystitis;

13. Clinical significant stress incontinence;

14. (Evident functional neurologic asymmetry).

Study design

Design

Study type:	Interventional
Intervention model:	Factorial
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2008
Enrollment:	54
Type:	Actual

Ethics review

Positive opinion

Date:	19-11-2007

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	NL1097
NTR-old	NTR1131
Other	Dept. of Urology, AZM, Maastricht : MEC 07-2-083
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A