Sacral neuromodulation test with bilateral first stage tined lead procedure in patients with non-obstructive urinary retention: A pilot study

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The objective of this study is to determine whether bilateral sacral nerve stimulation with FSTLP test is more effective than unilateral stimulation, among patients with non obstructive urinary retention.

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

Summary

ID

NL-OMON33635

Source
ToetsingOnline

Brief title
Bilateral neuromodulation test for urinary retention

Condition

- Bladder and bladder neck disorders (excl calculi)

Synonym
retention, urinary retention bladder

Research involving
Human

Sponsors and support

Primary sponsor: Urologie

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: bilateral stimulation, sacral neuromodulation, urinary retention

Outcome measures

Primary outcome

The primary endpoint is the eligibility for SNM therapy. This is defined as yes

or no. A patient is eligible for the therapy when he or she can void again or

the volume increased with at least 50%, and the catheterized volume is less

then 100ml.

Secondary outcome

Average voided volume and average catheterized volume

Study description

Background summary

Neuromodulation through stimulation of the sacral nerves is a promising therapeutic option in patients with symptoms of non-obstructive urinary retention that are refractory to conservative treatment.
Each candidate for sacral neuromodulation (SNM) therapy is tested with either a Percutaneous Nerve Evaluation test (PNE) or a first stage tined lead placement test (FSTLP) before definitive implantation. During this test period the integrity of the sacral nervous system and the reaction of the patient*s symptoms to SNM are evaluated. Before (baseline) and during the test phase, objective parameters such as the number of catheterizations per day, the voided volume and the postvoid residual urine volume, are recorded in voiding diaries. Patients that show an improvement of at least 50% in one of these parameters are considered good candidates for SNM therapy and are implanted with a definitive internal system.
Currently, both PNE and FSTLP tests are performed with unilateral stimulation of the sacral nerve either on the right or left side of the sacrum. If a patient shows no or less than 50% improvement of the objective parameters, he is considered a bad candidate for SNM and the electrodes are removed. This decision is currently based on a unilateral stimulation test. A study on

animals by Schultz-Lampel et al. suggests that bilateral sacral neuromodulation can be a more effective technique for voiding dysfunction. They conclude that bilateral stimulation may be more effective at lower stimulation intensities with positive side effects such as longer stimulator-battery life and less potential nerve damage. Clinical experience in different centers also suggests that bilateral test stimulation may give a greater improvement in parameters. Currently, only one prospective randomized crossover trial compared unilateral approach with bilateral sacral nerve stimulation. In that study 13 patients with urinary retention underwent unilateral as well as bilateral PNE test to assess the possible advantages of bilateral stimulation. All patients were stimulated during at least 72 hours in a unilateral and a bilateral setting with a washout period of at least 48 hours between these two test periods. Although the difference between unilateral and bilateral stimulation was not statistically significant, the volume per void did not increase significantly during unilateral stimulation but did increase significantly during bilateral stimulation. The catheterized volume decreased significantly with no difference between unilateral and bilateral stimulation. There were two patients who started voiding during bilateral stimulation, whereas during unilateral stimulation they were unable to void and still had to perform intermittent catheterization.
The test used in the study by Scheepens et al was PNE. There are a few important differences between the PNE and the FSTLP test. The advantage of PNE test is that it is cheaper and less invasive than FSTLP test. The bilateral FSTLP test is thus more expensive and more invasive. The removal of the lead is also more invasive after FSTLP than after PNE.
A disadvantage of PNE test is lead migration with loss of effect after a short time. This is not the case with FSTLP test because of the tines on the lead. Furthermore the effectiveness is different. A recent study by Leong et al. has shown that more patients with urinary retention responded to FSTLP than with PNE (64% vs. 18%) (unpublished).
The findings by Scheepens et al. together with recent findings by Leong et al. and the current patient population with retention are the basis for this study.

Study objective

The objective of this study is to determine whether bilateral sacral nerve stimulation with FSTLP test is more effective than unilateral stimulation, among patients with non obstructive urinary retention.

Study design

A prospective cross-over pilot study will be conducted to evaluate whether bilateral SNM test has an additional effect in patients with non obstructive urinary retention compared to unilateral.
All patients will be implanted with bilateral tined leads. Before the patients are implanted they are asked to fill out a voiding diary (baseline). The first

week after the implant they are asked to turn on the external pulse generator only on one side to simulate a unilateral test. Currently, no data are available that show or suggest a predominance of left or right side stimulation. The second week, stimulation side is changed. During the third week, patients are asked to turn the external pulse generator on both sides at the same time. During each week patients are asked to fill out self recorded voiding diaries for at least three days.

Intervention

In this study all patient will undergo FSTLP as usual but bilaterally instead of unilaterally. This means that two leads will be implanted instead of one. And both leads will be connected to an external pulse generator.

The settings during this study are exactly the same as usual care. Frequency of 10 Hz, pulse width of 210 µs. The patient can change the amplitude to any level between 0 and 10 volts. We ask the patient to keep the amplitude just below sensory threshold.

The first week patients are asked to turn on only one of the external pulse generator. This is to simulate a unilateral stimulation test. The second week patients are asked to repeat the same procedure but this time on the other side. The third week patients are asked to turn both external pulse generator on. During each week patients are asked to keep a voiding diary for at least three days.

If a patient has a good response unilaterally then the 2nd stage tined lead placement will follow together with the removal of the other lead. If a patient has only a good response bilaterally then the 2nd stage tined lead placement will follow on both sides. If a patient has no response at all then removal of both leads will follow.

Study burden and risks

Both PNE and FSTLP tests are usually conducted in a unilateral approach, stimulating a sacral nerve on either the right or left side of the sacrum. If a patient has no response to the test then complete failure of SNM therapy is assumed and the lead will be removed. However, there are some clinics that suggest conducting bilateral test stimulation to obtain better results. A study by Scheepens showed that among 13 patients with retention, two responded to only bilateral stimulation. A benefit for a patient who is included in this study is that he may have a greater possibility to respond to sacral neuromodulation, and therefore reduced need to intermittent catheterization.

Bilateral FSTLP procedure has in theory a higher risk of infection and bleeding due to a double number of wounds compared with unilateral. Because the risk

when conducting the FSTLP unilaterally is very small, we consider the risk for bilateral FSTLP to also be very small. The burden for the patient is minimal. The number of operations are the same, although the operation time is going to be around 15 minutes longer then unilateral FSTLP procedure. The period for unilateral and bilateral FSTLP test is equally long, although during bilateral FSTLP a patient has to fill out a voiding diary for in total of nine days instead of seven days.

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 (male and female), aged between 18-70 years, with urinary retention or voiding dysfunction, such as hesitancy or intermittency, that are due to an acontractile detrusor or to urethral sphincter dysfunction. The overactivity of the sphincter may occur in absence of

detrusor contraction and may be the cause of the lack of detrusor activity

Exclusion criteria

Known neurologic disease or impairment including DM (severe or uncontrolled diabetes; or diabetes with peripheral nerve involvement), spinal cord injury, MS

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2009
Enrollment:	12
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	06-07-2009
Application type:	First submission
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
ClinicalTrials.gov	NCT00878176
CCMO	NL26326.068.08