Acute effect on urodynamic measurements of sacral neuromodulation for treatment of idiopathic overactive bladder.

Published: 18-09-2017
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The aim is to determine the immediate effect of sacral neuromodulation on urodynamic measurements.

Ethical review	Approved WMO
Status	Pending
Health condition type	Bladder and bladder neck disorders (excl calculi)
Study type	Observational invasive

Summary

ID

NL-OMON44396

Source
ToetsingOnline

Brief title
Acute effect of SNM on UDS

Condition

- Bladder and bladder neck disorders (excl calculi)

Synonym
Idiopathic overactive bladder, overactive bladder

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Overactive bladder, Sacral neuromodulation, Urodynamic measurements, Urodynamics

Outcome measures

Primary outcome

The primary endpoint will be the difference in maximum cystometric capacity

seen on UDS before and after activation of the PNE.

Secondary outcome

Secondary parameters are bladder volume at: first sensation of bladder filling,

first desire to void, strong desire to void, first involuntary detrusor

contraction. The maximum increase in cmH2O during an involuntary detrusor

contraction and voiding diaries after 7 days of PNE.

Study description

Background summary

Overactive bladder is a difficult to treat common condition with a high burden on society. There is still lack of understanding the pathophysiology and conservative therapies are often ineffective. Sacral neuromodulation is a safe and effective alternative, however there is still much unknown about the acute effects om bladder function. In elaborating sacral neuromodulation more insight is necessary in the effect of sacral neuromodulation on urodynamic measurement.

Study objective

The aim is to determine the immediate effect of sacral neuromodulation on urodynamic measurements.

Study design

A prospective pilot study in which urodynamic measurements with and without sacral neuromodulation are compared.

Study burden and risks

No extra hospital visits are required when participating. The burden of the study is the urodynamic investigation at the day of electrode insertion instead of having a urodynamic investigation another day prior to the insertion of electrode.

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

- Have given informed consent.
- Have sufficient knowledge of the Dutch language to understand the informed consent form.
- Are at least 18 years of age.

- Have a voiding frequency of more than 8 times per 24 hours as determined by a voiding frequency chart of 2 days or have predominantly urge urinary incontinence every day at least once.
- Are not adequately treated for OAB with conservative treatment, like life style intervention, medication and pelvic floor therapy.

Exclusion criteria

- Have a positive urinalysis or urine culture.
- Have predominantly stress urinary incontinence.
- Have predominantly bladder pain syndrome.
- Have a neuropathic bladder.
- Have a symptomatic urinary tract infection.
- Have an indwelling catheter.
- Have had radiation therapy of the pelvis.
- Have a urethral stricture.
- Have had bladder cancer.
- Pregnancy.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2017
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO Date:	18-09-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL62538.078.17