Dorsal genital nerve sub-chronic stimulation implant in patients with overactive bladder syndrome

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To determine the clinical value of chronic implantation of an electrode adjacent to the dorsal genital nerve for conditional electrical stimulation in patients with overactive bladder syndrome The aim is to have >60-70% decrease in number of...

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

Summary

ID

NL-OMON38841

Source
ToetsingOnline

Brief title
DGN sub-chronic stimulation implant

Condition

- Bladder and bladder neck disorders (excl calculi)

Synonym
Oveactieve bladder, Urgency-incontinence

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Neurodan. Sofiendalsvej 85 - DK-9200 Aalborg - Denmark

Intervention

Keyword: Dorsal Genital nerve, Neurostimulation, Overactive bladder

Outcome measures

Primary outcome

Decrease in number of incontinence episodes per 24 h >60-70% of baseline

status.

Secondary outcome

NA

Study description

Background summary

Symptoms of overactive bladder syndrome with or without detrusor overactivity decrease quality of life. Not all patients respond satisfactorily to conservative therapies. Patient-controlled electrical stimulation of the dorsal genital nerve could be an alternative.

Study objective

To determine the clinical value of chronic implantation of an electrode adjacent to the dorsal genital nerve for conditional electrical stimulation in patients with overactive bladder syndrome The aim is to have >60-70% decrease in number of urgency incontinence episodes per 24 h.

Study design

Pilot study.

Intervention

Patients will complete voiding diaries for 3 days prior to the date of investigation. Patients will also complete an Urgency Severity Score sheet. An electrode lead (PNE set 3065USC) connected to Medtronic test stimulator 3625 will be implanted under local anaesthesia adjacent to the dorsal genital nerve, Patients will be able to activate the stimulator on conditional basis. Implants

will be explanted after 7 days. Patients will complete voiding diaries during the stimulation period and for 3 days after explanation.

Study burden and risks

At the first visit, information about the study and intervention will be given. The study intervention, with electrical stimulation, will be done at the second visit. The third visit is to explant the electrode. The patients don*t have any direct benefit, besides a reimbursement of travelling expenses and a gift coupon (¤50,-). The risk of the adverse events is thought to be minimal, because no vital organs are in the area of needle insertion. Possible risks are temporary pain due to needle insertion, pain due to hitting the pubic bone during electrode insertion and/or infection at the site of stimulation and puncture, and vascular or nerve damage by electrode insertion.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein zuid, Nijmegen 10
Nijmegen 6500HB
AF
Scientific
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein zuid, Nijmegen 10
Nijmegen 6500HB
AF

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

>18 y old
With urgency incontinence
Willing and aiming to follow all requirements of the protocol

Exclusion criteria

Patients with pure stress urinary incontinence
Patients with urinary tract infection
Patients with skin lesions at the site of implantation
Patients with cardiac pacemaker

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-09-2013
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Medtronic test stimulator 3625 with lead electrode PNE set 3065USC
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	25-07-2013
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	05-05-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL43219.091.13