Safety and Performance study of the C-Life Investigational Electrode for subject-controlled, on-demand, dorsal genital nerve stimulation to treat urgency urinary incontinence.

Published: 21-09-2015
Last updated: 19-04-2024

Objective: Safety and performance of the C-Life Investigational Electrode, and to determine the clinical value for conditional dorsal genital nerve stimulation in patients with overactive bladder syndrome.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Urinary tract signs and symptoms
Study type	Interventional

Summary

ID

NL-OMON42806

Source
ToetsingOnline

Brief title
Safety and Performance study of the C-Life Investigational Electrode

Condition

- Urinary tract signs and symptoms
- Renal and urinary tract therapeutic procedures

Synonym
urgency urinairy incontinence

Research involving
Human

Sponsors and support

Primary sponsor: Neurodan (Member of the Otto Bock Group)
Source(s) of monetary or material Support: research grant

Intervention

Keyword: dorsal genital nerve, Electrode, Neuromodulation, Urgency urinary incontinence

Outcome measures

Primary outcome

Safety and performance of the C-life Investigational Electrode.

Secondary outcome

Secondary outcomes:

Decrease in number or severity of incontinence episodes per 24 h >50% of

baseline status.

To record the electrode voltages during stimulation and the electrochemical

impedance spectra

Study description

Background summary

Rationale: Symptoms of overactive bladder syndrome with or without detrusor overactivity decrease quality of life, and not all patients respond satisfactorily to conservative therapies. Subject-controlled, on-demand, dorsal genital nerve stimulation could be an alternative.
Recently we conducted a pilot study on subject-controlled, on-demand, dorsal genital nerve stimulation with a test-electrode and obtained good results. Unfortunately with this test-electrode, it was not possible to fixate it internally, and it didn*t stay in the proper position over a longer period, in some subjects not even for the complete study period. A new electrode has been developed, the C-Life Investigational Electrode, that will fixate in the tissue surrounding the nerve in order to minimize the potential for migration of the electrode in the tissue.

Study objective

Objective: Safety and performance of the C-Life Investigational Electrode, and to determine the clinical value for conditional dorsal genital nerve stimulation in patients with overactive bladder syndrome.

Study design

Study design: Pilot study.

Intervention

Patients will complete voiding diaries and a padtest for 3 days prior to the date of investigation. Patients will also complete an Urgency Severity Score sheet. The C-Life Investigational Electrode will be implanted under local anesthesia adjacent to the dorsal genital nerve. It is connected percutaneously to the C-Life Investigational Stimulator, which is a modified version of the CE-marked MyGait Stimulator from Ottobock. Patients will be able to activate the stimulator on conditional basis. The implant will be explanted after 7 days. Patients will complete voiding diaries/padtest and once a day an Urgency severity Score during the stimulation period and for 3 days after explanation.
The stimulation threshold, the electrode voltage, and the impedance will be examined after implantation and before removal of the electrode

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 insertion. Possible risks are temporary pain due to the electrode insertion and/or infection at the site of stimulation and puncture, and vascular or nerve damage by electrode insertion.

Contacts

Public
Neurodan (Member of the Otto Bock Group)

Sofiendalsvej 85
Aalborg SV 9200
DK

Scientific
Neurodan (Member of the Otto Bock Group)

Sofiendalsvej 85
Aalborg SV 9200
DK

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

urgency urinairy incontinence

Exclusion criteria

neurological disease that cause the urgency urinairy incontinence

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):	29-03-2016
Enrollment:	5
Type:	Actual

Medical products/devices used

Generic name:	C-Life Investigational Electrode
Registration:	No

Ethics review

Approved WMO Date:	21-09-2015
Application type:	First submission
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	NL53729.091.15