Performance of the miniaturo*-I system for treatment of urinary urge incontinence.

Published: 03-04-2007
Last updated: 10-08-2024

To determine the performance (safety and effectiveness) of miniaturo*-I for the treatment of urinary urge incontinence.

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

Summary

ID

NL-OMON30732

Source
ToetsingOnline

Brief title
miniaturo*-I study for Urinary Urge Incontinence

Condition

- Bladder and bladder neck disorders (excl calculi)

Synonym
overactive bladder, Urge incontinence

Research involving
Human

Sponsors and support

Primary sponsor: American Medical Systems Inc.
Source(s) of monetary or material Support: American Medical Systems

Intervention

Keyword: efficacy, electromodulation, safety, urge incontinence

Outcome measures

Primary outcome

Improvement in number of incontinence episodes per day.

Secondary outcome

Clinical success rate at 3 months, 6 months and 12 months; number of serious

adverse events.

Study description

Background summary

Urge incontinence is due detrusor overactivity. Urgeincontinence is a disabling condition influencing quality of life. Treatment is not causative, often not effective and often has many side effects.
Electrical stimulation of the pelvic floor muscles diminishes detrusor overactivity and in that way improves urge incontinence.

Study objective

To determine the performance (safety and effectiveness) of miniaturo*-I for the treatment of urinary urge incontinence.

Study design

Prospective

Intervention

Electrical stimulation of the pelvic floor by an implantable electrostimulator and lead.

Study burden and risks

At least 5 visits to the outpatient clinic are required and 2 admissions,

taking approximately 15 hours plus 2 x 3 days in hospital. Before implantation a urodynamic test is performed and patients have to fill out questionnaires into quality of life and symptoms and need to keep a voiding diary every visit. There is a risk for infection or erosion of the implant, feeling of an electrical shock in the stimulation area, and urinary retention.

Contacts

Public
American Medical Systems Inc.

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Scientific
American Medical Systems Inc.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. At least 18 years old female and full body development
2. Signed informed consent
3. Normal mental status
4. Patient agrees to attend all follow-up evaluations and is willing to completely and accurately fill out voiding diaries and questionnaires, and is willing to complete required

exams and tests.
5. Patient who failed conservative treatments (i.e. lifestyle modification-fluid consumption, behavioral modification, and pharmacological therapy) for at least 6 months.
6. Overactive detrusor demonstrated on cystometry during the last 6 months or patients who are regarded as sensory urgency
7. Urinary Urge Incontinence greater then 5 episodes per day
8. Urinary frequency greater than 10 times/day and 3 times/night
9. Patients with competent sphincter mechanism
10. Patients with normally functioning upper urinary tract
11. Passing MTS-I session

Exclusion criteria

1. Previous participation in another study with any investigational drug or device within the past 3 months
2. Any active implant (cardiac or other)
3. Previous urinary incontinence surgery or implantation of artificial graft material within the last 6 months
4. Any spinal or genitourinary surgery within the last 6 months
5. Previous abdominoperineal resection of the rectum or radical hysterectomy within the last 6 months
6. Anatomical defects that preclude use of the device
7. PVR> 100 ml
8. VLPP > 100 cmH2O on urodynamic testing
9. Primary pelvic pain syndrome
10. Obvious clinically demonstrated genuine stress incontinence
11. Presence of cystocele, enterocele or rectocele of grade 3 or 4 (if applicable)
12. Any neurological disease or disorder
13. Current urinary tract infection or chronic inflammation, presence of urinary stone and/or urinary tract malignancy (i.e. tumor, urethritis, vesicourethral reflux, etc.)
14. Pelvic radiotherapy and chemotherapy
15. Morbid obesity
16. Severe uncontrolled diabetes
17. Any severe heart disease
18. Patients requiring frequent magnetic resonance imaging (MRI) exams
19. Current pregnancy or attempting to get pregnant (female patient)
20. Patient with uncontrolled bleeding coagulopathy.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-06-2007
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	miniaturo tm-I system
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	03-04-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
Other	cp 01017
CCMO	NL14669.041.06