Performance of the miniaturo™-I system for treatment of overactive bladder.

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23310

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Urge incontinence caused by detrusor overactivity

Sponsors and support

Primary sponsor: American Medical Systems, Inc.
10700 Bren Road West
Minnetonka, MN 55343 USA
Tel: 952-930-6000
Fax: 952-930-6007

Intervention

Outcome measures

Primary outcome

Improvement in number of leaking episodes/day.

Secondary outcome

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

Study description

Background summary

Title:

Performance of the miniaturo™-I system for treatment of overactive bladder

Running title: miniaturo™-I study for Urinary Urge Incontinence.

Design:

Prospective, interventional and feasibility study.

Number of patients:

Up to 30.

Patients:

Patients with Urinary Urge Incontinence.

Clinical sites:

Up to 10 sites.

Purpose:

To determine the performance (safety and effectiveness) of miniaturo™-I for the treatment of UUI.

Primary endpoint:

Improvement in number of leaking episodes/day.

Secondary endpoints:

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

Methods:

Urodynamic test, Voiding diary, Test stimulation, Device implantation, Incontinence and Quality of life questionnaires.

Clinical Follow-up:

1, 3, 6 and 12 months.

Study objective

urge incontinence is caused by overactivity of the detrusor muscle of the urinary bladder. Electrical stimulation of the pelvic floor muscles can suppress detrusor overactivity. The miniaturo tm-i system is designed to deliver mild electrical stimulation to the pelvic floor muscles in a minimally invasive way.

Study design

N/A

Intervention

Electrical stimulation of the pelvic floor muscles by an implantable electrical device.

Contacts

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Eligibility criteria

Inclusion criteria

1. Females > 18 years;

2. Failed conservative treatment for > 6 mnths;

3. Detrusor overactivity on urodynamic study;

4. Urinary urge incontinence > 5 episodes a day;

5. Urinary frequency > 10/day and > 3/night;

6. Competent sphincter mechanism;

7. Normal upper tract;

8. Passing MST-I session.

Exclusion criteria

1. Participation in another study < 3 mnths;

2. Any active implant;

3. Incontinence surgery < 3 mnths;

4. Spinal or genital surgery < 6 mnths;

5. Post void residual > 100 ml;

6. Leak point pressure > 100 cm H2O;

7. Pelvic pain syndrome;

8. Stress incontinence;

9. Cystocele/rectocele/enterocele grade 3 or 4;

10. Neurological disease;

11. Morbid obesity;

12. Severe uncontrolled diabetes;

13. Severe heart disease;

14. Requiring frequent MRI exams;

15. Pregnancy or ettemp to get pregnant;

16. Uncontrolled bleeding coagulopathy.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2006
Enrollment:	30
Type:	Actual

Ethics review

Not applicable
Application type: Not applicable

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
NTR-new	NL767
NTR-old	NTR778
Other	: CP-01-017
ISRCTN	ISRCTN08364639

Study results

Summary results
N/A