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

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 28/12/2006 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 28/12/2006 | Completed | [_] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 04/01/2007 | Urological and Genital Diseases | [_] Record updated in last year |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
CP-01-017

## Study information

**Scientific Title**

**Study objectives**

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™-I system is designed to deliver mild electrical stimulation to the pelvic floor muscles in a minimally invasive way.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Not provided at time of registration

### Primary study design
Interventional

### Study design
Prospective, interventional, feasibility study

### Study type(s)
Treatment

### Health condition(s) or problem(s) studied
Urge incontinence

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

### Intervention Type
Other

### Phase
Not Specified

### Primary outcome(s)
Improvement in number of leaking episodes/day

### Key secondary outcome(s)
1. Clinical success rate at three months, six months and 12 months
2. Number of serious adverse events

### Completion date
30/11/2007

## Eligibility

### Key inclusion criteria
1. Females more than 18 years
2. Failed conservative treatment for more than six months
3. Detrusor overactivity on urodynamic study
4. Urinary urge incontinence more than five episodes a day

5. Urinary frequency more than 10/day and more than 3/night
6. Competent sphincter mechanism
7. Normal upper tract
8. Passing MST-I session

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

### Sex
Female

### Key exclusion criteria
1. Participation in another study less than three months
2. Any active implant
3. Incontinence surgery less than three months
4. Spinal or genital surgery less than six months
5. Post void residual less than 100 ml
6. Leak point pressure more than 100 cm Water (H2O)
7. Pelvic pain syndrome
8. Stress incontinence
9. Cystocele/rectocele/enterocele grade three or four
10. Neurological disease
11. Morbid obesity
12. Severe uncontrolled diabetes
13. Severe heart disease
14. Requiring frequent Magnetic Resonance Imaging (MRI) exams
15. Pregnancy or attempt to get pregnant
16. Uncontrolled bleeding coagulopathy

### Date of first enrolment
01/12/2006

### Date of final enrolment
30/11/2007

## Locations

### Countries of recruitment
Netherlands

**Study participating centre**
**University Medical Center Utrecht (UMCU)**
Utrecht
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# Sponsor information

**Organisation**
University Medical Center Utrecht (UMCU) (The Netherlands)

**ROR**
https://ror.org/0575yy874

# Funder(s)

**Funder type**
Industry

**Funder Name**
American Medical Systems, Inc. (USA)

# Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration