ISRCTN08364639 https://doi.org/10.1186/ISRCTN08364639

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
Netherlands
3584 CX

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