Multicentered randomized controlled trial to test the cost effectiveness of urodynamics in women with symptoms of stress urinary incontinence in whom surgical treatment is considered.

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To test the value of preoperatively performed urodynamics with regard to outcome of surgery for stress urinary incontinence (SUI) and to examine whether not performing urodynamics preoperatively is more cost effective than performing urodynamics...

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

Summary

ID

NL-OMON30485

Source
ToetsingOnline

Brief title
Urodynamics prior to stress urinary incontinence surgery

Condition

- Urinary tract signs and symptoms
- Uterine, pelvic and broad ligament disorders
- Obstetric and gynaecological therapeutic procedures

Synonym
Urinary incontinence. Unintentional urinary loss.

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMW subsidie

Intervention

Keyword: Cost effectiveness, Stress urinary incontinence, Surgical treatment, Urodynamics

Outcome measures

Primary outcome

Primary outcome: Non inferiority of the improvement of the UDI one year after

treatment in the non urodynamics group.

Secondary outcome

Secondary outcomes: Cure of incontinence as measured with pad test and voiding

diary. Complications of surgery for stress incontinence in particular

re-operation and overactive bladder symptoms of quality of life as measured by

validated questionnaires.

Study description

Background summary

The urodynamic investigations that differentiate between several types of stress urinary incontinence and thus tailor the specific type of operation, lack validation and predictive value in individual cases. It is therefore questionable whether it can predict the therapeutic effect as well as the risk of complications like de novo urgency and urinary retention. Moreover, since the introduction of easy to administer midurethral polypropylene slings, every type of SUI is treated in the same way and therefore probably no urodynamic investigation for that purpose needs to be done.

Study objective

To test the value of preoperatively performed urodynamics with regard to outcome of surgery for stress urinary incontinence (SUI) and to examine whether not performing urodynamics preoperatively is more cost effective than performing urodynamics preoperatively using the non-inferiority assumption.

Study design

Study design:
Multicentre, randomised controlled multidisciplinary trial.

Intervention

Intervention: stress urinary incontinence therapy based on history, clinical examination, pad test and 48h voiding diary versus therapy based on the same parameters AND urodynamic findings

Study burden and risks

Burden: Five outpatient visits (of which one contains the ususal prostoperative visit), with 48h-Bladder(voiding and incontinence) diary, pad test, urinalysis, ultrasound to measure residual urine and completion of questionnaire.
Risk: possibly increased risk of complications like de novo urgency and urinary retention in non-urodynamics group.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

All women, not previously operated for stress incontinence, seeking help for urinary stress incontinence where conservative therapy in particular physiotherapy has failed and are opting and candidates for surgical therapy can participate in the study. Incontinence must have been demonstrated on physical examination and/or micturition diary. Patients can be included by gynaecologists or urologists who are cooperating in the study.

Exclusion criteria

Women with a history of urge incontinence.
Women with previous urinary incontinence surgery.
Women incapable to read and speak Dutch.
Women not giving informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2007
Enrollment:	290
Type:	Anticipated

Ethics review

Approved WMO
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

ID: 24532
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL14625.091.06
OMON	NL-OMON24532