Protocol for the Value of Urodynamics prior to Stress Incontinence Surgery (VUSIS) study: a multicenter randomized controlled trial to assess the cost effectiveness of urodynamics in women with symptoms of stress urinary incontinence in whom surgical treatment is considered.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24532

Source
Nationaal Trial Register

Brief title
VUSIS

Health condition

urodynamics
stress incontinence
urodynamisch onderzoek
stressincontinentie

Sponsors and support

Primary sponsor: ZonMw: The Netherlands Organisation for Health Research and Development
Source(s) of monetary or material Support: ZonMw: The Netherlands Organisation for Health Research and Development.
Projectnumber 945-07-203.

Intervention

Outcome measures

Primary outcome

The primary outcome of this study is clinical improvement of incontinence as measured with the validated Dutch version of the UDI.

Secondary outcome

Secondary outcomes of this study include costs, cure of incontinence as measured with voiding diaries, complications such as re-operation or overactive bladder symptoms, and quality of life.

Study description

Background summary

Background:

Stress urinary incontinence (SUI) is a common problem. In the Netherlands, yearly 64.000 new patients, of whom 96% are women, consult their general practitioner because of urinary incontinence. Approximately 7500 urodynamic evaluations and approximately 5000 operations for SUI are performed every year. In all major national and international guidelines from both gynaecological and urological scientific societies, it is advised to perform urodynamics prior to invasive treatment for SUI, but neither its effectiveness nor its cost-effectiveness has been assessed in a randomized setting.

The Value of Urodynamics prior to Stress Incontinence Surgery (VUSIS) study evaluates the positive and negative effects with regard to outcome, as well as the costs of urodynamics, in women with symptoms of SUI in whom surgical treatment is considered.

Study design:

A multicentre diagnostic cohort study will be performed with an embedded randomized controlled trial among women presenting with symptoms of (predominant) SUI.
Urinary incontinence has to be demonstrated on clinical examination and/or voiding diary. Physiotherapy must have failed and surgical treatment needs to be under consideration. Patients will be excluded in case of previous incontinence surgery, in case of pelvic organ prolapse more than 1 centimeter beyond the hymen and/or in case of residual bladder volume of more than 150 milliliter on ultrasound or catheterisation.

Patients with discordant findings between the diagnosis based on urodynamic investigation and the diagnosis based on their history, clinical examination and/or micturition diary will be randomized to operative therapy or individually tailored therapy based on all available information.
Patients will be followed for two years after treatment by their attending urologist or gynaecologist, in combination with the completion of questionnaires.

Six hundred female patients will be recruited for registration from approximately twenty-seven hospitals in the Netherlands. We aspect that one hundred and two women with discordant findings will be randomized.

The primary outcome of this study is clinical improvement of incontinence as measured with the validated Dutch version of the Urinary Distress Inventory (UDI). Secondary outcomes of this study include costs, cure of incontinence as measured by voiding diary parameters, complications related to the intervention, re-interventions, and generic quality of life changes.

Study objective

For this study our hypothesis was that there is no difference between outcome of surgery and individually tailored therapy in women with a discrepancy between urodynamic findings and findings from other investigations, such as history and clinical examination. In case of confirmation of this hypothesis, urodynamic investigation in women with predominant SUI could be safely omitted.

Study design

T=0, follow-up at 6 weeks, 6, 12 en 24 months.

Intervention

Midurethral sling procedure versus individual treatment.

Contacts

Public
Radboud University Nijmegen Medical Centre
791, Dept of Obstetrics and Gynecology
PO Box 9101
Sanne Leijsen van
Radboud University Nijmegen Medical Centre
791, Dept of Obstetrics and Gynecology
Nijmegen 6500 HB
The Netherlands
+31 641520114
Scientific
Radboud University Nijmegen Medical Centre
791, Dept of Obstetrics and Gynecology
PO Box 9101
Sanne Leijsen van
Radboud University Nijmegen Medical Centre
791, Dept of Obstetrics and Gynecology
Nijmegen 6500 HB
The Netherlands
+31 641520114

Eligibility criteria

Inclusion criteria

1. Symptoms of stress urinary incontinence and/or mixed urinary incontinence, predominantly stress incontinence;

2. Signs of stress urinary incontinence on physical examination or voiding diary;

3. Patient is a candidate for surgical treatment (as based on history and physical examination);

4. Patient has attended at least 3 months of pelvic floor exercises;

5. Patient is capable to fill out bladder diaries, pad tests and questionnaires and understands the Dutch written and spoken language.

Exclusion criteria

1. Previous incontinence surgery;

2. Mixed urinary incontinence, urge component is predominant;

3. Pelvic organ prolapse > 1cm beyond the hymen on Valsalva in supine position;

4. Post void urinary residual > 150ml on ultrasound or catheterisation;

5. Additional pelvic surgery (prolapse and/or hysterectomy);

6. Patient is or wants to become pregnant;

7. Prior pelvic radiotherapy.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2008
Enrollment:	600
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-06-2009

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 30485
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1761
NTR-old	NTR1871
CCMO	NL14625.091.06
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON30485

Study results

Summary results
N/A