Vaginal prolapse repair and mid urethral sling procedure in women with genital prolapse and predominant stress urinary incontinence.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24511

Source
Nationaal Trial Register

Brief title
CUPIDO-1

Health condition

1. Genital prolapse;

2. stress urinary incontinence.

Sponsors and support

Primary sponsor: Academic Medical Center (AMC) Department of Gynaecology
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

Absence of urinary (stress) incontinence and subsequent treatment for urinary (stress) incontinence.

Secondary outcome

1. Anatomical results and repeated treatment for pelvic organ prolapse;

2. Disease specific and general quality of life;

3. Morbidity and quality adjusted life-years;

4. General satisfaction;

5. Costs.

Study description

Background summary

Pelvic organ prolapse and stress urinary incontinence co-exist in about 40% of the women with genital prolapse. Because the TVT has been proven to be as successful as the Burch colposuspension in the treatment of stress incontinence, combining vaginal prolapse repair with a mid urethral sling procedure in these women has become an attractive treatment option. Concomitant surgery showed to be an effective treatment for stress urinary incontinence in observational studies. However, literature about possible adverse effects such as obstructive voiding symptoms and detrusor overactivity is not consistent. Besides, concomitant surgery will result in over treatment as the correction of a cystocele showed a 5-year success rate of 37% in the relief of stress incontinence. Thus, concomitant surgery will probably result in less postoperative complaints of stress incontinence but may lead to adverse effects and over treatment. The objective of the CUPIDO-1-trial is to determine whether vaginal prolapse repair is equally effective as concomitant vaginal surgery in women with genital prolapse and symptoms of stress urinary incontinence.

Study objective

Compared to vaginal prolapse repair, concomitant vaginal surgery in women with genital prolapse and predominant stress urinary incontinence decreases the risk of postoperative urinary incontinence without increasing other lower urinary tract symptoms.

Study design

6 weeks, 6 months, 12 months.

Intervention

Only vaginal prolapse repair or vaginal prolapse repair combined with mid urethral sling procedure.

Contacts

Public
Dept. Gynaecology
Martini Hospital
PO Box 30.033

Marinus Ploeg van der
Groningen 9700 RM
The Netherlands
+31 (0)50-5247700
Scientific
Dept. Gynaecology
Martini Hospital
PO Box 30.033

Marinus Ploeg van der
Groningen 9700 RM
The Netherlands
+31 (0)50-5247700

Eligibility criteria

Inclusion criteria

Women undergoing vaginal prolapse surgery for stage 2 or more genital prolapse with predominant stress urinary incontinence.

Exclusion criteria

1. Age < 19 year;

2. Mentally disabled or in any other way unable to give informed consent;

3. Pregnancy or the intention to become pregnant in the future;

4. < 12 months post partum (delivery or other termination after 20 weeks);

5. Prior surgery for urinary incontinence;

6. Recent pelvic surgery such as prolapse surgery and hysterectomy (< 6 months);

7. History of bladder or urethral surgery or known lower urinary tract anomaly (ie. diverticulum);

8. Systemic disease known to affect bladder function (ie. Parkinson's disease, MS, spina bifida);

9. Planned or current cancer chemotherapy or radiotherapy;

10. Participation in another treatment intervention trial that might influence trial results;

11. Sign of chronic retention defined as > 300 mL. retention after normal voiding. 12. isolated posterior compartment prolapse.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2007
Enrollment:	126
Type:	Actual

Ethics review

Positive opinion

Date:	28-01-2008
Application type:	First submission

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	NL1154
NTR-old	NTR1197
Other	AMC Amsterdam, The Netherlands : MEC 05/286 # 07.17.1758
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A