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

No registrations found.

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

## Summary

### ID

NL-OMON25481

**Source**
Nationaal Trial Register

**Brief title**
CUPIDO 2

**Health condition**

Pelvic Organ Prolapse, genital prolapse, genitale prolaps, genitale verzakking.
Stress urinary incontinence, stressincontinentie, inspannings incontinentie.

### Sponsors and support

**Primary sponsor:** Jan Paul W.R. Roovers, MD PhD
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**Source(s) of monetary or material Support:** N/A

## 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

Continent women have a 11-20% risk to develop stress urinary incontinence after prolapse repair. This risk is thought to be highest in women with pre-operative masked or occult stress incontinence. Occult stress incontinence is the finding of stress incontinence after reduction of the prolapse in women without complaints of urinary incontinence. In these cases, stress incontinence is masked by an urethral obstruction caused by the genital prolapse. It is unknown which test to demonstrate occult stress incontinence is best in predicting postoperative stress incontinence and how high this risk is.

The CARE trial has recently shown that the use of a Burch colposuspension at the time of an abdominal sacrocolpopexy decreases the risk of postoperative urinary incontinence without increasing other lower urinary tract symptoms. 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 alternative. Concomitant surgery showed to be an effective treatment for occult stress 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 most continent women will not develop postoperative stress incontinence. Thus, the benefit of adding a mid urethral sling

procedure to prevent stress urinary incontinence at the time of vaginal prolapse repair is unclear. The objective of the CUPIDO-2-trial is to determine whether vaginal prolapse repair is equally effective as concomitant vaginal surgery in women with genital prolapse and occult stress urinary incontinence.

### Study objective

Compared to vaginal prolapse repair, concomitant vaginal surgery in women with genital prolapse and occult 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

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# Eligibility criteria

## Inclusion criteria

Women undergoing vaginal prolapse surgery for stage 2 or more genital prolapse with pre-operative occult 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 or symptom of urinary incontinence;

12. Sign of chronic retention defined as > 300 mL. retention after normal voiding.

# Study design

### Design

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|---|---|
| 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): | 01-10-2007 |
| Enrollment: | 160 |
| Type: | Actual |

## Ethics review

Positive opinion

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|---|---|
| Date: | 17-10-2007 |
| 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 | NL1038 |

| Register | ID |
|---|---|
| NTR-old | NTR1070 |
| Other | AMC Amsterdam, The Netherlands : MEC 05/286 # 06.17.0165 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd |

# Study results

**Summary results**

1. Roovers JP, Oelke M. Clinical relevance of urodynamic investigation tests prior to surgical correction of genital prolapse: a literature review. Int Urogynecol J Pelvic Floor Dysfunct. 2007;18:455-60.<br>
2. Roovers JP, van Laar JO, Loffeld C, Bremer GL, Mol BW, Bongers MY. Does urodynamic investigation improve outcome in patients undergoing prolapse surgery? Neurourol Urodyn. 2007;26(2):170-5.