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

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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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25481

Bron
Nationaal Trial Register

Verkorte titel
CUPIDO 2

Aandoening

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

Ondersteuning

Primaire sponsor: Jan Paul W.R. Roovers, MD PhD
Dept. Gynaecology
Academical Medical Centre Amsterdam
PO Box 22660
1100 DD Amsterdam
The Netherlands
t. +31 (0)20-5669111

J.P.Roovers@amc.uva.nl
Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

6 weeks;

6 months;

12 months.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Dept. Gynaecology
Martini Hospital
PO Box 30.033

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

Wetenschappelijk

Dept. Gynaecology
Martini Hospital
PO Box 30.033

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

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Women undergoing vaginal prolapse surgery for stage 2 or more genital prolapse with pre-operative occult stress urinary incontinence.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-10-2007
Aantal proefpersonen:	160
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	17-10-2007
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1038
NTR-old	NTR1070
Ander register	AMC Amsterdam, The Netherlands : MEC 05/286 # 06.17.0165
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

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.
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.