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

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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...

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

Samenvatting

ID

NL-OMON24511

Bron
Nationaal Trial Register

Verkorte titel
CUPIDO-1

Aandoening

1. Genital prolapse;

2. stress urinary incontinence.

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC) Department of Gynaecology
Overige ondersteuning: fund = initiator = sponsor

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

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.

Doel van het onderzoek

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.

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

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Women undergoing vaginal prolapse surgery for stage 2 or more genital prolapse with predominant 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 of chronic retention defined as > 300 mL. retention after normal voiding. 12. isolated posterior compartment prolapse.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-11-2007
Aantal proefpersonen:	126
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	28-01-2008
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	NL1154
NTR-old	NTR1197
Ander register	AMC Amsterdam, The Netherlands : MEC 05/286 # 07.17.1758
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A