Avaulta versus anterior colporraphy

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With usage of mesh material (Avaulta anterior) in the treatment of a cystocele >/ 2 with complaints a better anatomical result is achieved in comparence with the standard treatment (anterior colporraphy).

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

Samenvatting

ID

NL-OMON21781

Bron
Nationaal Trial Register

Verkorte titel
Avaulta versus anterior colporraphy

Aandoening

anterior prolapse surgery; cystocele
In het Nederlands:
vaginale prolaps chirurgie; cystocele

Ondersteuning

Primaire sponsor: University Medical Center Utrecht (UMCU)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The number of women who will have a recurrence, defined as a stage ¡Ý 2 anterior vaginal prolapse at 2 years follow-up.

Toelichting onderzoek

Achtergrond van het onderzoek

OBJECTIVE:

After a standard surgical anterior colporrhaphy for an anterior vaginal wall prolapse (cystocele) grade 2 or higher, one-third of women will have an anatomical recurrence within 2 years after primary surgery. The use of a non-absorbable synthetic polypropylene mesh has been shown to be effective in repeat surgery for genital prolapse, with a recurrence rate between 3-12%. However, a comparative study between the anterior colporrhaphy and surgery with a non-absorbable synthetic mesh as primary treatment for an anterior vaginal wall prolapse has not been conducted.

The objective of this study is to compare the clinical and cost-effectiveness of an anterior colporrhaphy repair with a cystocele repair using a non-absorbable synthetic Avaulta mesh.

STUDY DESIGN:

Multicentre prospective randomised controlled trial.

STUDY POPULATION:

Women 40 -80 years of age with a cystocele stage 2 or higher, according to the POPQ classification, who are scheduled for primary surgery.

INTERVENTION:

Women are either allocated to a group who will undergo a classic anterior colporraphy repair or a group in which the Avaulta mesh is used.

OUTCOME MEASURES:

The primary endpoint of the study is the number of women who will have a recurrence, defined as a stage ¡Ý 2 anterior vaginal prolapse at 2 years follow-up. Secundary endpoints are:

- The effect of surgery on urogenital symptoms and quality of life

- Complications of surgery (direct and medium term)

- Cost-effectiveness analysis.

POWER / DATA ANALYSIS:

Assuming that in the standard anterior colporrhaphy group 35% of women will have a recurrent cystocele stage ¡Ý 2 at the 2 year follow up and an estimated recurrence rate of 10% in the Avaulta anterior group , 50 women have to be assigned to each group (power 0,80, alpha 0.05). With an estimated drop-out of 15%, a total of 115 women have to be randomized.

TIME-SCHEDULE:

38 months: 12 months for inclusion, 24 months follow-up and 2 months analysis and report.

Doel van het onderzoek

With usage of mesh material (Avaulta anterior) in the treatment of a cystocele >/ 2 with complaints a better anatomical result is achieved in comparence with the standard treatment (anterior colporraphy).

Onderzoeksopzet

Pre-operative, 6 weeks, 3, 6,12 and 24 months postoperative

Onderzoeksproduct en/of interventie

Women are either allocated to a group who will undergo a classic anterior colporraphy repair or a group in which the Avaulta® mesh is used

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Women aged 40-80 years

2. Cystocele stage ¡Ý 2 according to POP Q classification

3. No previous anterior colporraphy

4. Good understanding of Dutch language in word en writing

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Women with childbearing potential who do not use adequate contraceptive measures (hormonal contraceptives, barrier methods (condoms), intra uterine device, male vasectomy,

sterilisation).

2. History of major gynaecological or urological surgery, with the exception of a hysterectomy for reasons other than a genital prolapse.

3. History of cancer or severe cardiopulmonary disease

4. Conditions that might interfere with a successful conduction and completion of the study in the opinion of the specialist (language problems, cognitive dysfunction, etc)

5. Recurrent lower urinary tract infections (> 3 culture proven infections/year)

6. Maximum bladder capacity < 300 ml (bladder diary)

7. Urinary stress incontinence with an indication for surgical correction.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	23-05-2007
Aantal proefpersonen:	115
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	14-07-2008

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	NL674
NTR-old	NTR1376
Ander register	MEC : 06-264
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A