Avaulta versus anterior colporraphy

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21781

Source
NTR

Brief title
Avaulta versus anterior colporraphy

Health condition

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

Sponsors and support

Primary sponsor: University Medical Center Utrecht (UMCU)

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

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

- Complications of surgery (direct and medium term)

- Cost-effectiveness analysis.

Study description

Background summary

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.

Study objective

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).

Study design

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

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

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-05-2007
Enrollment:	115
Type:	Anticipated

Ethics review

Positive opinion

Date:	14-07-2008
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	NL674
NTR-old	NTR1376
Other	MEC : 06-264
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A