A randomized controlled trial of anterior colporraphy and PerigeeTM as surgical correction of symptomatic cystocele.

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To study which technique is most effective to surgically correct a symptomatic cystocele.2. To compare morbidity and post-operative recovery of anterior colporraphy and PerigeeTM.3. To compare the need for repeated pelvic floor surgery following...

Ethical review	Approved WMO
Status	Pending
Health condition type	Bladder and bladder neck disorders (excl calculi)
Study type	Interventional

Summary

ID

NL-OMON30369

Source
ToetsingOnline

Brief title
Anterior colporraphy versus Perigee

Condition

- Bladder and bladder neck disorders (excl calculi)
- Obstetric and gynaecological therapeutic procedures

Synonym
cystocele, prolapse of the anterior vaginal wall

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cystocele, disease specific quality of life, prolapse surgery, randomized controlled trial

Outcome measures

Primary outcome

Disease specific quality of life.

Secondary outcome

1. Morbidity

2. Duration of catheter use

3. POP-Q score (Anatomical effect)

4. General quality of life

5. Performed surgical procedures in the first year after primary cystocele

repair.

Study description

Background summary

Anterior colporraphy has been the standard surgical procedure to correct a cystocele. The risk on recurrence after this procedure is high. PerigeeTM is a new surgical procedure to correct cystocele. During this procedure a polypropylene mesh is placed between the anterior vaginal wall and the bladder. We aim to study whether anterior colporraphy or PerigeeTM is preferable in patients undergoing cystocele repair.

Study objective

To study which technique is most effective to surgically correct a symptomatic cystocele.
2. To compare morbidity and post-operative recovery of anterior colporraphy and PerigeeTM.
3. To compare the need for repeated pelvic floor surgery following anterior

colporraphy and PerigeeTM.

Study design

A randomized controlled trial will be performed

Intervention

Anterior colporraphy or perigee

Study burden and risks

All patients are asked to complete a questionnaire before and at 6 weeks, 3 months and 12 months after surgery. Patients hold a diary from the day of surgery until 6 weeks after surgery. Patients visit the hospital for additional visits at 3 months and 12 months after surgery.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients who are candidate to undergo surgical correction of cystocele.

Exclusion criteria

Patients who simultaneously have to undergo surgical correction of vault prolapse or rectocele are excluded. Patients who simultaneously have to undergo vaginal hysterectomy or stress-incontinence surgery are not excluded.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2007
Enrollment:	76
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL14963.018.06