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

No registrations found.

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

Summary

ID

NL-OMON24040

Source
NTR

Brief title
Perigee trial

Health condition

Symptomatic cystocele
(NLD: Symptomatische cystocele).

Sponsors and support

Primary sponsor: Investigator initiated study
Source(s) of monetary or material Support: Self funded

Intervention

Outcome measures

Primary outcome

Quality of life related to pelvic floor function.

Secondary outcome

1. Morbidity;

2. POP-Q classification of the prolapse;

3. General quality of life.

Study description

Background summary

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 that is applied by a transobturator approach appears to be effective. However there is a lack of randomized controlled trials comparing this new approach to conventional anterior colporraphy.
The purpose of this randomized controlled trial is to compare the effects of anterior colporraphy and PerigeeTM as surgical correction of symptomatic cystocele.

Study objective

This trial hypothesizes that there are differences in morbidity and efficacy between both surgical techniques. It is also hypothesized that PerigeeTM is less morbid compared to anterior colporraphy as it is a minimal invasive technique. We can not hypothesize on the efficacy of the compared techniques.

Study design

6 weeks, 3 months and 12 months after surgery.

Intervention

Women are either allocated to classic anterior colporraphy repair or to cystocele using PerigeeTM.

Contacts

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Eligibility criteria

Inclusion criteria

Women undergoing primary or secondary surgical repair of cystocele stage 2 or higher, according to the POP-Q classification.

Exclusion criteria

1. Patients with an indication for posterior vaginal wall repair;

2. Patients with an indication for hysterectomy;

3. Patients in whom the anterior vaginal wall is not the most descending part of the prolapse.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2006
Enrollment:	90
Type:	Anticipated

Ethics review

Positive opinion

Date:	18-11-2007
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	NL1099
NTR-old	NTR1134
Other	MEC : 06/264
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A