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

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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...

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

Samenvatting

ID

NL-OMON24040

Bron
NTR

Verkorte titel
Perigee trial

Aandoening

Symptomatic cystocele
(NLD: Symptomatische cystocele).

Ondersteuning

Primaire sponsor: Investigator initiated study
Overige ondersteuning: Self funded

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Quality of life related to pelvic floor function.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

6 weeks, 3 months and 12 months after surgery.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-07-2006
Aantal proefpersonen:	90
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	18-11-2007
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	NL1099
NTR-old	NTR1134
Ander register	MEC : 06/264
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A