Primary treatment of vaginal prolapse: Pessary use versus prolapse surgery.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24754

Source
Nationaal Trial Register

Brief title
ROK

Health condition

English:
Pelvic Organ Prolapse
Pessary
Prolapse surgery

Dutch:
Prolaps
Verzakking
Pessarium
Ring
Prolapschirurgie

Sponsors and support

Primary sponsor: Maxima Medical Centre
Source(s) of monetary or material Support: Maxima Medical Centre

Intervention

Outcome measures

Primary outcome

The primary outcome will be disease specific quality of life, which will be evaluated by using the urogenital distress inventory (UDI).

Secondary outcome

1. General quality of life and patients satisfaction rate. Both will be evaluated by using a validated questionnaire (werkgroepbekkenbodem, eurqol, SF-36);

2. Successful continuous pessary treatment;

3. Anatomical result. Evaluated through pelvic examination according to the recommendations of the ICS.

Study description

Background summary

ROK is a randomized controlled trial of pessary use versus prolapse surgery in patients with POP-Q stage 2-4 pelvic organ prolapse who are eligible for both treatments. The primary outcome is disease specific quality of life. Secondary outcomes are general quality of life, satisfaction, anatomical results and successful continuous pessary use.

Study objective

Whether the use of pessary therapy is successful against vaginal prolapse or not might be predictable. A higher age of the patient at baseline, and succeeding pessary therapy for the period of one month is plausible associated with prolonged pessary use. On the other hand, discomfort of pessary use during the first month could be associated with failure of pessary therapy. Furthermore a certain sexual activity level and a preference for prolapse surgery might predict the failure rate.

Study design

1. Pre-treatment: POP-Q and questionnaire;

2. 6 weeks post treatment: Questionnaire;

3. 6 months post treatment: Questionnaire;

4. 1 years post treatment: POP-Q and questionnaire.

Intervention

Pessary:

1. Portex;

2. Falk.

Prolapse surgery:

1. Vaginal hysterectomy;

2. Anterior colporrhaphy;

3. Posterriorcolporrhaphy;

4. A combination of above-mentioned surgical treatments;

5. A combination of above-mentioned surgical treatments including MESH material.

Contacts

Public
Polikliniek gynaecologie, tav A.Coolen
Postbus 7777
A.L.W.M. Coolen
Veldhoven 5500 MB
The Netherlands
Scientific
Polikliniek gynaecologie, tav A.Coolen
Postbus 7777
A.L.W.M. Coolen
Veldhoven 5500 MB
The Netherlands

Eligibility criteria

Inclusion criteria

1. POP-Q stage grade 2-4 (POP-Q according to ICS);

2. Eligible for pessary treatment and prolapse surgery.

Exclusion criteria

1. Isolated rectocele;

2. Previous prolapse treatment;

3. Previous treatment against urine incontinence.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2010
Enrollment:	80
Type:	Actual

Ethics review

Positive opinion

Date:	17-04-2011
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	NL2719
NTR-old	NTR2856
Other	MEC Maxima Medical Care : 0826
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A