Primary treatment of vaginal prolapse, pessary use versus prolapse surgery. A comparison of quality of life.

Published: 14-09-2009
Last updated: 06-05-2024

see Background

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Obstetric and gynaecological therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON33706

Source
ToetsingOnline

Brief title
Pessary versus prolaps surgery

Condition

- Obstetric and gynaecological therapeutic procedures

Synonym
prolapse

Research involving
Human

Sponsors and support

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

Intervention

Keyword: pessary, prolapse surgey, treatment, vaginal prolapse

Outcome measures

Primary outcome

The primary outcome will be disease specific quality of life, as measured with

the urogenital distress inventory (UDI).

Secondary outcome

Secondary outcomes will be women*s perceived improvement in the prolapse

symptoms, clinicians grading of prolapse at one year of follow-up.

Study description

Background summary

Objective: Pelvic organ prolapse is a common condition in women. Almost 50% of the women will deal with this problem during lifetime. Vaginal vault prolapse can be treated with two completely different strategies; i.e. pessary use or prolapse surgery. Both strategies are efficacious treatments, with each having their own advantages and disadvantages. However, studies directly comparing both treatments are lacking. We therefore designed a randomised clinical trial on the subject. In this trial, we look at the disease specific quality of life after randomisation between pessary use and prolapse surgery. We also compare general quality of life, anatomic results, cost-effectiveness and the contributiveness to therapy.

Study objective

see Background

Study design

Randomised Controlled Trial.

Study burden and risks

Questionairres of 30 minutes (4 times). One extra visit to the hospital with an gynaecology examination.

Contacts

Public
Máxima Medisch Centrum

de run 4600
5500 VB Veldhoven
Nederland
Scientific
Máxima Medisch Centrum

de run 4600
5500 VB Veldhoven
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Vaginal prolapse stage 2-4 (POP-Q criteria, ICS).

Exclusion criteria

Prolapse surgery of incontinence surgery in the history

Study design

Design

Study phase:	2
Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2009
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	14-09-2009
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL24091.015.08