Pessary or surgery for symptomatic pelvic organ prolapse

Published: 25-11-2014
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The primary objective is to compare the effectiveness and cost-effectiveness of pessary versus surgery as initial treatment formoderate to severe symptomatic pelvic organ prolapse (POP) in women at two year after initiation of treatment.The...

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

Summary

ID

NL-OMON47134

Source
ToetsingOnline

Brief title
PEOPLE - PEssary Or ProLapse surgEry

Condition

- Obstetric and gynaecological therapeutic procedures

Synonym
Prolapse

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Pessary, POP, Prolapse, Surgery

Outcome measures

Primary outcome

Primary outcome: Global impression of improvement of POP symptoms at 24 months

measured with PGI-I

Secondary outcome

Secondary outcomes:

* Changes in symptom bother and disease-specific quality of life at 12 and 24

months follow-up

* Changes of sexual function at 12 and 24 months follow-up

* Changes in general quality of life at 3, 6, 12 and 24 months.

* Adverse events/complications related to both treatment strategies during the

study period

* Development of prediction model to identify factors for failing of pessary

and surgery.

* Costs-effectiveness analyses

Study description

Background summary

Moderate to severe pelvic organ prolapse symptoms can be treated with pessary or surgery. Both treatments appear to be effective, but have not been compared directly.

Study objective

The primary objective is to compare the effectiveness and cost-effectiveness of pessary versus surgery as initial treatment for
moderate to severe symptomatic pelvic organ prolapse (POP) in women at two year after initiation of treatment.
The secondary objective is the development of a prediction model for failure of pessary use and surgery within 2 years.

HYPOTHESIS
The strategy of pessary as initial therapy is as effective as direct surgery for moderate to severe POP, but it is associated with
lower costs.

Study design

Multicenter pragmatic cohort study with an embedded randomised controlled non-inferiority trial comparing pessary therapy versus surgery including an economic evaluation.

Intervention

Pessary therapy or POP surgery

Study burden and risks

SAMPLE SIZE
With 198 women per group, we will have 80% power to reject the null hypothesis that pessary therapy is inferior to surgery, with
a 1-sided alpha of 0.05, a non-inferiority margin of 10% and the proportion in the standard group is 80%.
Accounting for 10% loss to follow-up we plan to randomize 436 patients.

ANTICIPATED HEALTHCARE EFFICIENCY GAIN
Annually a total budget impact of 10-14 million euro health care costs for comparable health outcomes and 20-28 million euro
economic impact on society.

FEASIBILITY
The project group is experienced in performing large-scale intervention studies. The study will be performed within our Dutch
national obstetrics and gynaecology consortium. This consortium infrastructure has proven to be very effective.

TIME SCHEDULE
48 months

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

1. Women with a prolapse stage 2 or more.
2. Women with moderate to severe POP symptoms. Moderate to severe POP symptoms is defined as a prolapse domain score > 33 on the validated Dutch version of the Pelvic Floor Distress Inventory (PFDI-20).
3. Women who have had a successful pessary fitting procedure: for the RCT.
4. Written informed consent

Exclusion criteria

1. Prior urogynaecological (prolapse or incontinence) surgery
2. Probability of future childbearing

3. Insufficient knowledge of the Dutch language
4. Co-morbidity causing increased surgical risks
5. Major psychiatric illness
6. Prior pessary use

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-03-2015
Enrollment:	436
Type:	Actual

Ethics review

Approved WMO

Date:	25-11-2014
Application type:	First submission
Review commission:	METC NedMec

Not approved

Date:	30-12-2014
Application type:	Amendment
Review commission:	METC NedMec

Approved WMO

Date:	27-01-2015
Application type:	Amendment
Review commission:	METC NedMec

Approved WMO Date:	10-02-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	12-02-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	25-02-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	02-03-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	06-03-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	15-04-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	23-06-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	25-08-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	01-09-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	

Date:	22-09-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	14-10-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	19-02-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	14-03-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	29-03-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	03-05-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	13-05-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	19-10-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	27-10-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	

Date:	09-11-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	07-12-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	01-03-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	10-05-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	28-03-2018
Application type:	Amendment
Review commission:	METC NedMec

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	NL50717.041.14