Sacrospinous ligament fixation versus Elevate Posterior procedure in treatment of primary apical prolapse stage * 2: a multi-center randomised controlled trial.

Published: 13-03-2012
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To compare the effects of Elevate Posterior procedure versus sacrospinous ligament fixation on pelvic floor function.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive tract disorders NEC
Study type	Interventional

Summary

ID

NL-OMON37357

Source
ToetsingOnline

Brief title
Elevate Posterior trial

Condition

- Reproductive tract disorders NEC
- Obstetric and gynaecological therapeutic procedures

Synonym
Pelvic organ prolapse

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W,American Medical Systems, Inc.

Intervention

Keyword: Mesh, Prolapse, Sexual function, Surgery

Outcome measures

Primary outcome

Quality of life related to pelvic floor function measured using validated

disease-specific quality of life questionnaires (UDI, DDI, IIQ)

Secondary outcome

Sexual function at one year after intervention measured using the PISQ-12

questionnaire, POP-Q, morbidity (including post-operative pain, complications

and recovery of normal daily activities), generic quality of life, repeated

pelvic floor surgery within 12 months after intervention and cost analysis.

Study description

Background summary

Pelvic organ prolapse is a common health problem, with a life time risk to undergo surgery of 11%. When dealing with an apical compartment prolapse the most frequent proposed procedure is sacrospinous ligamant fixation, but recently a mesh procedure (Elevate Posterior) was introduced. Although mesh is not recommended as primary procedure based on objectified adverse effects like exposure, pelvic pain and dyspareunia, there is theoretical basis to believe that for apical prolapse, Elevate Posterior is beneficial compared to native tissue repair. We propose a multi-center RCT comparing sacropinous ligament fixation to Elevate Posterior in primary apical compartment prolapse.

Study objective

To compare the effects of Elevate Posterior procedure versus sacrospinous ligament fixation on pelvic floor function.

Study design

A multi-center, randomised, controlled trial

Intervention

Elevate Posterior or sacrospinous ligament fixation

Study burden and risks

As we compare two strategies that are already applied in current clinical practice, no additional risks from both procedures are expected. Evaluation will take place after 6 weeks (routine post-operative consultation), by telephone after 6 months and patients will be invited for one extra visit to the hospital at 12 months (in some hospitals also a routine post-operative consultation).

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

Sexually active women with a primary apical compartment prolapse stage * 2 requiring surgery.

Exclusion criteria

- Previous prolapse surgery
- Enterocele stage * 2 after hysterectomy (performed for other reasons than prolapse)
- Known malignancy
- Pregnancy or wish to become pregnant
- Unwilling to return for follow-up or language barriers
- Presence of immunological / haematological disorders interfering with recovery after surgery
- Abnormal ultrasound findings of uterus or ovaries.

Study design

Design

Study type:	Interventional
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):	21-03-2013
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	13-03-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-06-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-08-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-11-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Not approved Date:	28-03-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 27804
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL38240.018.11
OMON	NL-OMON27804