Sacrospinous ligament fixation or Elevate Posterior procedure in treatment of primary apical prolapse stage * 2: a matched cohort study.

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

Ethical review	Not approved
Status	Will not start
Health condition type	Obstetric and gynaecological therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON39017

Source
ToetsingOnline

Brief title
Elevate Posterior Cohort

Condition

- 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, Primary, Prolapse, Surgery

Outcome measures

Primary outcome

Quality of life related to pelvic floor function after 12 months 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 matched cohort study 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 matched cohort study

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

Women with a primary apical compartment prolapse stage * 2 requiring surgery. Patients with co-existing posterior defects or concomitant perineal surgery (perineoplasty) can be included.

Exclusion criteria

- Previous prolapse surgery
- Women of reproductive age desiring future pregnancy and childbirth
- Unwilling to return for follow-up or language barriers
- Co-morbidity that is associated with increased surgical risks, for instance women with ASA 3 or 4 classification. Up to the physician to decide.
- Poor cognitive function, as subjectively assessed by the physician.
- History of or current major psychiatric illness as subjectively assessed by the physician.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	105
Type:	Anticipated

Ethics review

Not approved

Date:	15-07-2013
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL44443.018.13