Sacrospinous ligament fixation combined with anterior colporrhaphy versus Elevate Anterior procedure in treatment of primary apical and anterior compartment prolapse stage >= 2: a multi-center randomised controlled trial.

Published: 13-03-2012
Last updated: 15-05-2024

To compare the effects of sacrospinous ligament fixation combined with anterior colporrhaphy versus Elevate Anterior procedure on pelvic floor function.

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

Summary

ID

NL-OMON41517

Source
ToetsingOnline

Brief title
Elevate Anterior 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, 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 measured using the PISQ-12 questionnaire (if applicable),

POP-Q, morbidity (including post-operative pain, complications and recovery of

normal daily activities), disease specific and generic quality of life,

repeated pelvic floor surgery within 36 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%. Many patients have a combination of different compartments involved in the prolapse of which the most prevalent combination is apical and anterior compartment prolapse. Sacrospinous ligament fixation combined with anterior colporrhaphy is the most frequent proposed procedure, but recently a mesh procedure (Elevate Anterior) was introduced that covers both compartments in one procedure. 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 the combination of apical and anterior compartment prolapse, Elevate Anterior is beneficial compared to native tissue repair. We propose a multi-center RCT comparing the combination of sacropinous ligament fixation and anterior colporraphy to Elevate Anterior in primary apical and anterior compartment prolapse.

Study objective

To compare the effects of sacrospinous ligament fixation combined with anterior colporrhaphy versus Elevate Anterior procedure on pelvic floor function.

Study design

A multi-center randomised controlled trial.

Intervention

Elevate Anterior or sacrospinous ligament fixation combined with anterior colporrhaphy

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 an extra visit to the hospital at 12, 24 and 36 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

Women with a primary apical and anterior 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):	19-07-2012
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:	21-06-2012
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
Approved WMO Date:	10-07-2013
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-01-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-01-2015
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: 25045
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL38228.018.11
OMON	NL-OMON25045