A RCT of direct- versus indirect bilateral- sacrospinous ligament fixation for surgical correction of apical prolapse stage 2 or more.

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1. To asses non-inferiority of BSC mesh in surgical success (= anatomic cure, subjective improvement and no re-treatment necessary) in the treatment of apical prolapse compared to unilateral SSLF at 12 months;2. Improvement of quality of life...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Uterine, pelvic and broad ligament disorders
Study type	Interventional

Summary

ID

NL-OMON47591

Source
ToetsingOnline

Brief title
SDI Trial, Sacrospinous ligament fixation: Direct or Indirect

Condition

- Uterine, pelvic and broad ligament disorders
- Obstetric and gynaecological therapeutic procedures

Synonym
Pelvic Organ Prolapse, Prolapse of the vagina

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Agency for Medical Innovations

Intervention

Keyword: BSC-mesh, Prolapse, Prolapse surgery, Sacrospinous ligament fixation

Outcome measures

Primary outcome

1. Surgical success (= anatomic cure, subjective improvement and no

re-treatment necessary) in the treatment of apical prolapse compared to

unilateral SSLF at 12 months;

2. Improvement of quality of life related to pelvic floor function at 12 months

after surgery (PFDI-20).

Secondary objectives

Secondary outcome

1. Morbidity (Pain, ADL, hospital stay, surgical parameters, postoperative

recovery, blood loss);

2. Quality of life score (PFDI-20): improvement stratified by compartment;

3. Sexual satisfaction (PISQ-12) improvement from baseline

4. To asses superiority of BSC mesh in surgical success (anatomic cure,

subjective improvement and no re-treatment necessary) in the treatment of

apical prolapse compared to unilateral SSLF at 12 months when non-inferiority

has been proven;

5. Procedure related serious adverse events.

Study description

Background summary

Pelvic organ prolapse (POP) is a condition in which pelvic organs descend into the vagina, resulting in problems with micturition (i.e. urinary incontinence or incomplete voiding), defecation (i.e. constipation or fecal incontinence) or sexual functioning (i.e. dyspareunia). *** POP is very common with an estimated prevalence of 30%. ***If the patient is bothered by symptoms, surgery is proposed which is usually performed vaginally. At the moment long term results of POP surgery are far from optimal with reported recurrence rates up to 40%. One out of three POP operations is performed for recurrent prolapse, and some patients even undergo numerous operations. ***

Unilateral Sacrospinous Ligament Fixation (SSLF) is the recommended treatment option for patients suffering from apical POP. In unilateral SSLF, the top of the vagina is sutured to the sacrospinous ligament. Unilateral SSLF has an objective cure rate of 85-90% and has a relatively low recurrence rate. Complications in SSLF are rare; A review of 22 studies that in total included 1229 patients reported severe bleeding in just three patients (0.2%). *** However, because of the direct fixation to the sacrospinous ligament, unilateral SSLF could result in an anatomical alteration of the vagina and the rectum in which there will be a posterior deviation which can have consequences on voiding, defecation and sexual function.

Bilateral fixation as compared to unilateral fixation is - as a result of the distal fixation of sutures - supposed to be more effective, because there is no posterior deviation of the vagina. Bilateral fixation using non-absorbable sutures has shown optimal anatomical results (94.3% objective and 93% subjective cure) and improved quality of life after surgery. ***

Bilateral Sacrospinous Colposuspension (BSC) using synthetic mesh, however, could even result in an anatomy that is similar to the original nulliparous anatomy. A better anatomical repair could be associated with a positive effect on sexual outcome, voiding and defecation.
Also, using mesh for a posterior sacral fixation of the vaginal top has shown a lower risk of recurrence.

Study objective

1. To asses non-inferiority of BSC mesh in surgical success (= anatomic cure, subjective improvement and no re-treatment necessary) in the treatment of apical prolapse compared to unilateral SSLF at 12 months;
2. Improvement of quality of life related to pelvic floor function at 12 months

after surgery (PFDI-20).

Study design

A multicentre non-inferiority randomized-controlled trial to compare unilateral sacrospinous ligament fixation with bilateral sacrospinous colposuspension using polypropylene macropore mesh. Follow up of 12 months.

Intervention

nvt

Study burden and risks

Baseline: physical examination (POP Q) and 3 questionnaires
The first week patients will keep a diary about experienced discomfort.
6 weeks after surgery: physical examination and 3 questionnaires
6 months after surgery: 2 guestionnairs
12 months after surgery: physical examination and 4 questionnaires

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. Subject is female;
2. Subject is least 18 years of age;
3. Subject has at least a stage 2 apical prolapse and is planned to undergo vaginal surgical correction.

Exclusion criteria

1. Subjects who are pregnant or want to become pregnant;
2. Subjects who are not capable of giving informed consent;
3. Subject has a known sensitivity to polypropylene;
4. Subject has an indication for a concomitant procedure to treat SUI;
5. Subject is known with pelvic organ cancer (e.g. uterine, ovarian, bladder or cervical);
6. Subject has chronic systemic pain that includes the pelvic area or chronic focal pain that involves the pelvis;
7. Subject has a known neurologic or medical condition affecting bladder function (e.g. multiple sclerosis, spinal cord injury or stroke with residual neurologic deficit).

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-07-2018

Enrollment:	95
Type:	Actual

Medical products/devices used

Generic name:	Vaginal Mesh
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	08-09-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-11-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-12-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-10-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-11-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-01-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-10-2020

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: 22473
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL60451.018.17