Evaluation of two vaginal surgical procedures for the treatment of pelvic organ prolapse: unilateral (direct) and bilateral (indirect) sacrospinous ligament fixation.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22473

Source
NTR

Brief title
SDI-trial

Health condition

pelvic organ prolapse, prolapse, uterine prolapse, vaginal vault prolapse

Sponsors and support

Primary sponsor: Academic Medical Center (AMC), Amsterdam
Source(s) of monetary or material Support: AMC and A.M.I (Agency for Medical Innovations GmbH)

Intervention

Outcome measures

Primary outcome

1. Surgical success in the treatment of apical prolapse: The primary outcome measure will be surgical “success” or “failure” assessed one year after surgery. The primary outcome measure has three components:

- An anatomic assessment of prolapse, using the POPQ examination

- The presence or absence of bulge symptoms specific to prolapse, using two questions from the PFDI-20 questionnaire;

- An assessment of additional treatment (surgical or non-surgical) for prolapse after the index surgery.

2. Improvement of quality of life related to pelvic floor function: PFDI-20 questionnaire.

Secondary outcome

- Morbidity

- Quality of life related to pelvic floor function, stratified by compartment

- Sexual satisfaction improvement from baseline

- Superiority of BSC-mesh in the treatment of apical prolapse

- Procedure related serious adverse events

Study description

Background summary

Pelvic organ prolapse is a common condition. Unilateral sacrospinous ligament fixation (SSF) is the recommended treatment option for patients suffering from POP in the apical compartment. It has high objective cure rates and relatively low recurrence rates. However direct fixation will lead to a posterior deviation of the vaginal axis, which leads to an anatomical alteration of the vagina and rectum. This can have possible consequences on voiding, defecation and sexual function. Also, this might lead to an increase of stress on the anterior compartment and to a higher risk of developing a cystocele.

It is hypothesized that bilateral sacrospinous colposuspension using a polypropylene mesh (BSC mesh) is non-inferior in surgical success and superior in improvement of quality of life

related to the pelvic floor as compared to unilateral SSF with sutures.

This is a multicenter, non-inferiority, randomized-controlled trial for women with at least a stage 2 apical prolapse (according to the International Continence Society) who are planned to undergo vaginal surgical correction.

Study objective

It is hypothesized that bilateral sacrospinous colposuspension using a BSC mesh is non-inferior in surgical success and superior in improvement of quality of life related to the pelvic floor as compared to unilateral sacrospinous ligament fixation with suturus (SSF).

Study design

Baseline

Operation

Post-operation: 6 weeks, 6 months, 12 months

Intervention

- Unilateral Sacrospinous Ligament Fixation: Unilateral SSF is the recommended treatment option for patients suffering from apical POP. In SSF, the top of the vagina is sutured with non-degradable sutures to the sacrospinous ligament, most commonly to the right side to prevent lesions of the rectum.

- The Bilateral Sacrospinous Colposuspension using BSC-mesh: the BSC Mesh is designed to induce the formation of neo-ligaments by establishing symmetrical, bilateral suspension of the vaginal vault from the sacrospinous ligament. It recreates the support previously provided by the natural ligaments which are no longer functioning.

Contacts

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Eligibility criteria

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
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-04-2018
Enrollment:	144
Type:	Anticipated

Ethics review

Positive opinion

Date:	18-04-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47591
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6979
NTR-old	NTR7168
CCMO	NL60451.018.17
OMON	NL-OMON47591

Study results