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

Gepubliceerd: 18-04-2018 Laatst bijgewerkt: 15-05-2024

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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22473

Bron
Nationaal Trial Register

Verkorte titel
SDI-trial

Aandoening

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

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC), Amsterdam
Overige ondersteuning: AMC and A.M.I (Agency for Medical Innovations GmbH)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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).

Onderzoeksopzet

Baseline

Operation

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

Onderzoeksproduct en/of interventie

- 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.

Contactpersonen

Publiek

Kamer: H4-240

K.W.J. (Kim) Verhorstert
Meibergdreef 9

Amsterdam 1105 AZ
The Netherlands
020-5661973

Wetenschappelijk

Kamer: H4-240

K.W.J. (Kim) Verhorstert
Meibergdreef 9

Amsterdam 1105 AZ
The Netherlands
020-5661973

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	23-04-2018
Aantal proefpersonen:	144
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	18-04-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47591
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten