Sacrospinous ligament fixation versus Elevate Posterior procedure in treatment of primary prolapse.

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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...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27804

Bron
NTR

Verkorte titel
Elevate Posterior trial

Aandoening

Pelvic organ prolapse. Surgery. Mesh. Recurrence. Sexual function.

Vaginale verzakking. Chirurgie. Mesh/implantaat. Recidief. Seksuele functie.

Ondersteuning

Primaire sponsor: University Medical Center
Overige ondersteuning: fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Sexual function at one year after intervention measured using the PISQ-12.

Toelichting onderzoek

Achtergrond van het onderzoek

Sacrospinous fixation versus Elevate Posterior procedure in treatment of primary apical compartment prolapse stage >= 2: a multi-center randomised controlled trial.

Rationale:

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 RCT comparing sacropinous ligament fixation to Elevate Posterior in primary apical compartment prolapse.

Objective:

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

Study design:

A multi-center, randomised, controlled trial.

Study population:

Inclusion criteria: sexually active women with apical compartment prolapse stage >= 2 requiring surgical treatment. Exclusion criteria: previous prolapse surgery and enterocele stage >= 2 after hysterectomy.

Intervention:

Elevate Posterior or sacrospinous ligament fixation.

Main study parameters/endpoints:

Primary outcome: sexual function at one year after intervention measured using the PISQ-12. Secondary outcomes: 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 12 months after intervention and cost analysis.

Sample size calculation:

A difference of 10% from the maximum PISQ score (maximum score is 48, 10% being 4.8) was considered to be clinical relevant. To detect a difference in means of 4,8, with a power of 90% and an alpha level of 0.05, 42 patients in each group are needed. Anticipating on a 15% drop-out rate, we intend to include 100 patients (50 patients in each arm)

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

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).

Doel van het onderzoek

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 RCT comparing sacropinous ligament fixation to Elevate Posterior in primary apical compartment prolapse.

Onderzoeksopzet

Primary endpoint:

To compare the effects of sacrospinous ligament fixation to Elevate Posterior on sexual function measured using the PISQ-12 one year after intervention.

The PISQ-12 is a 12-item questionnaire with responses measured on a 5-point Likert scale, which evaluates sexual function of women with UI or POP and is divided into 3 domains: Behavioral Emotive, Physical, and Partner- Related. The Behavioral Emotive domain evaluates sexual desire, frequency of sexual activity, and orgasmic capabilities, whereas the Physical domain assesses more directly the effect of UI on sexual function. The Partner-Related domain assesses the patient's perception of her partner's response to the effect of her pelvic floor disorder on their sexual functioning, as well as her partner's sexual functioning.

Secondary endpoints:

1. Objective cure. Anatomical outcome will be be assessed by a POP-Q test pre- en postoperatively. A recurrence is defined as POP-Q stage 2 or more;

2. Pain, hospital stay, post- operative recovery. During hospitalisation till the first 6 weeks after surgery all patients are asked to keep a diary. Documented in this diary are: post-operative pain score (measured by the Visual Analogue Scale, on the evening after operation and then daily until the 7th day post-operative and then at 2 weeks and 6 weeks post-operative), used pain medication (daily from day 1 till 7 days post-operative and thereafter at 2 weeks and 6 weeks post-operative), general daily functioning (pre-operative and 1, 2 and 6 weeks post-operative) and number of days from operation till recovery to normal daily activities. After 6 weeks patients will receive a second diary in which they will document all visits to the hospital or physiotherapist because of complications or complaints related to the operation. The used pain medication during hospitalisation will be documented by the patient together with the nurse caring for the patient. Administration of morfine is finished as soon as possible and patients will use paracetamol and/or diclofenac. Used pain medication will be documented in the diary;

3. Subjective outcome will be assessed by validated disease-specific quality of life questionnaires (UDI, DDI, IIQ) and for the cost analysis general quality of life will be assessed by a standardized general quality of life questionnaire (EQ-5). These questionnaires will be filled in pre-operative and 6 weeks and 12 months post-operative;

4. Complications. The following complications will be registered: injury of bladder, bowel, nerve, vessel; buttock pain, haemorrhage/haematoma requiring transfusion and/or surgical intervention, urinary tract infection, retention bladder, fever or infection requiring antibiotics;

5. Repeated surgery within 12 months after intervention will be registered.

Onderzoeksproduct en/of interventie

Elevate Posterior or sacrospinous ligament fixation.

Contactpersonen

Publiek

PO Box 22660

Jan-Paul W.R. Roovers
Department of Obstetrics and Gynaecology
Academic Medical Center (AMC)
Meibergdreef 9, H4-140-1
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5666429

Wetenschappelijk

PO Box 22660

Jan-Paul W.R. Roovers
Department of Obstetrics and Gynaecology
Academic Medical Center (AMC)
Meibergdreef 9, H4-140-1
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5666429

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Previous prolapse surgery;

2. Enterocele stage 2 or more after hysterectomy (performed for other reasons than prolapse);

3. Known malignancy;

4. Pregnancy or wish to become pregnant;

5. Unwilling to return for follow-up or language barriers;

6. Presence of immunological / haematological disorders interfering with recovery after surgery;

7. Abnormal ultrasound findings of uterus or ovaries.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2012
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 37357
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2928
NTR-old	NTR3075
CCMO	NL38240.018.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON37357

Resultaten

Samenvatting resultaten
N/A