Sacrospinous ligament fixation combined with cystocele repair versus Elevate Anterior procedure in treatment of primary prolapse.

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

Samenvatting

ID

NL-OMON25045

Bron
Nationaal Trial Register

Verkorte titel
Elevate Anterior 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

Quality of life related to pelvic floor function at one year after intervention measured using UDI, DDI and IIQ questionnaires.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Rationale:

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 colporraphy is the most frequent proposed procedure, but recently a mesh procedure (Elevate Anterior PC) 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 PC 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 PC in primary apical and anterior compartment prolapse.

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.

Study population:

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

Intervention:

Elevate Anterior PC or sacrospinous ligament fixation combined with anterior colporrhaphy

Main study parameters/endpoints:

Primary outcome: quality of life related to pelvic floor function at one year after intervention measured using UDI, DDI and IIQ questionnaires. Secondary outcomes: sexual function measured using the PISQ-12, POP-Q, morbidity (including post-operative pain, complications and recovery of normal daily activities), generic quality of life, repeated pelvic floor surgery within 12 months after intervention and cost analysis.

Sample size:

The primary outcome in this study is quality of life related to pelvic floor function in patients subjected to Elevate Anterior PC or sacrospinous ligament fixation combined with anterior colporrhaphy surgery. A difference in reduction of the prolapse domain score (of the UDI) between both surgical techniques of 20% is considered to be a clinically relevant difference between the groups. With a power of 90% and an alpha level of 0.05, the calculated sample size necessary is 38 in each group. With an estimated drop-out of 15%, a total of 45 women in each group have to be randomized.
One of the secondary outcome variables in this study is sexual function in patients subjected to Elevate Anterior PC or sacrospinous ligament fixation combined with anterior colporrhaphy surgery. We aim to power this study to also sufficiently assess this secondary outcome. A difference of 10% from the maximum PISQ score (maximum score is 48, 10% being 4.8) was considered to be clinical relevant. Previous studies from Altman et al. have shown mean PISQ-scores 12 months after surgery of 35.1 for the vaginal native tissue repair group. Based on this expected value in the native tissue group and 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). 50 women in each treatment arm will be sufficient to assess a statistically significant difference in the primary outcome as well as the secondary outcome.

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%. 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 colporraphy 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.

Onderzoeksopzet

Primary endpoint:

To compare the effects of sacrospinous ligament fixation combined with anterior colporrhaphy to Elevate Anterior PC on quality of life related to pelvic floor function measured using validated disease-specific quality of life questionnaires (UDI, DDI, IIQ).

UDI: The Urogenital Distress Inventory is a standardized questionnaire measuring urogenital symptoms and is validated for the Dutch population (van der Vaart 2003). The questions cover the following five sections: urinary incontinence, overactive bladder, pain, obstructive micturition and prolapse. A high score on a particular section means more inconvenient symptoms.

DDI: The Defecatory Distress Inventory is a standardized questionnaire measuring defecatory symptoms (Roovers 2005). The questions cover the following sections: obstructive defecation, constipation, fecal incontinence and pain related to defecation. Again, a high score on a particular section means more inconvenient symptoms.

IIQ: The Incontinence Impact Questionnaire is disease-specific quality of life questionnaire covering the following sections: physical functioning, mobility, emotional functioning, social functioning and embarrassment.

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. Sexual function measured using the PISQ-12 questionnaire;

3. 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. Patients are allowed to maximally use 4,000 mg of paracetamol and/or 300 mg of diclofenac daily. Within these limits they are free to decide how much pain medication they will take, also when they are dismissed from the hospital. Used pain medication will be documented in the diary;

4. Cost analysis. For the cost analysis general quality of life will be assessed by a standardized general quality of life questionnaire (EQ-5);

5. 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;

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

Onderzoeksproduct en/of interventie

Elevate Anterior or sacrospinous ligament fixation combined with anterior colporrhaphy.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Sexually active women with a primary apical and anterior 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:	01-05-2012
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	19-09-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41517
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2927
NTR-old	NTR3074
CCMO	NL38228.018.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON41517

Resultaten

Samenvatting resultaten
N/A