Laparoscopic sacrocolpopexy versus vaginal sacrospinous fixation for vaginal vault prolapse.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21070

Source
Nationaal Trial Register

Brief title
SALTO-2

Health condition

Pelvic organ prolapse, vault prolapse, laparoscopic sacrocolpopexy, sacrospinous fixation

Sponsors and support

Primary sponsor: Máxima Medical Center
Source(s) of monetary or material Support: Máxima Medical Center

Intervention

Outcome measures

Primary outcome

The primary outcome is disease specific quality of life during a follow-up period of one year using the Dutch validated version of the Urinary Distress Inventory (UDI).

Secondary outcome

Secondary outcome will be the effect of the surgical treatment on prolapse related symptoms, post-operative recovery, procedure related morbidity, sexual function, quality of life, anatomical results using the POP-Q classification until one year follow-up, type and number of re-interventions, costs and cost-effectiveness and long term complications.

Study description

Background summary

Rationale/Objective:

It has been estimated that one in nine women will undergo a hysterectomy during lifetime. Up to 10% of the women who had a hysterectomy because of prolapse symptoms, will subsequently need surgical repair for vaginal vault prolapse thereafter. A variety of different surgical procedures to correct vaginal vault prolapse have been reported1. The reconstructive techniques can principally be divided into vaginal or abdominal procedures.

No prospective comparative studies of VSF and LSC are performed. Literature shows that abdominal sacrocolpopexy is better than vaginal sacrospinous fixation in terms of a lower recurrence and dyspareunia rate although operation time and hospital stay is longer. However hospital stay in laparoscopic sacrocolpopexy is shorter compared to the abdominal technique. This suggests that laparoscopic sacrocolpopexy might be a preferable treatment option for a vaginal vault prolapse. However, prospective trials comparing VSF and LSC are lacking. The aim of this randomized study is to compare the short- and long-term outcome of the VSF and LSC5,6,10.

Study design:

Multicentre prospective randomized controlled trial.

Study population:

Women with a posthysterectomy symptomatic vaginal vault prolapse.

Intervention:

Random allocation to vaginal sacrospinous fixation or laparoscopic sacrocolpopexy.

Main study parameters/endpoints:

Primary outcome is disease specific quality of life during a follow-up period of one year. Secondary outcome will be the effect of the surgical treatment on prolapse related symptoms, sexual functioning, procedure related morbidity, hospital stay, post-operative recovery, anatomical results using the POP-Q classification until one year follow-up, type and number of re-interventions, costs and cost-effectiveness.

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

As this study compares two common treatment regimens, it will not impose extra risk on the participants. Participants fill out questionnaires at 4 different moments, which will take them about 15 minutes at each occasion. Physical examination will be performed pre-operative, six weeks post-operative and the last examination will be done after one year.

Study objective

Based on the literature, we expect that the laparoscopic sacrocolpopexy will be equally or more successful in correction of vault prolapse as compared to vaginal sacrospinous fixation.

Study design

Participants fill out questionnaires at 4 different moments, which will take them about 15 minutes at each occasion. Physical examination will be performed pre-operative, six weeks post-operative and the last examination will be done after one year.

Intervention

1. Laparoscopic sacrocolpopexy;

2. Vaginal sacrospinous fixation.

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

1. Symptomatic vault prolapse POP-Q grade 2 which needs surgical treatment;

2. Eligible for both surgical treatments.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

1. Previous surgical treatment of vault prolapse;

2. Contra-indication for a surgical intervention;

3. Incapacitated patients.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2013
Enrollment:	74
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3811
NTR-old	NTR3977
Other	CCMO : ABR44799
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A