Laparoscopic sacrocolpopexy versus open abdominal sacrocolpopexy for vaginal vault prolapse: A long-term follow-up on quality of life and anatomical result

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To evaluate long-term outcome (3-10 years) in terms of quality of life, subjective and anatomic failure and erosion after laparoscopic versus open abdominal sacrocolpopexy as a treatment for vaginal vault prolapse in patients with a history of...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Uterine, pelvic and broad ligament disorders
Study type	Observational invasive

Summary

ID

NL-OMON45282

Source
ToetsingOnline

Brief title
SALTO-1: Long-term follow-up

Condition

- Uterine, pelvic and broad ligament disorders

Synonym
pelvic organ prolapse

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: Geen financiering beschikbaar

Intervention

Keyword: pelvic organ prolapse, sacral colpopexy, sacrocolpopexy, vault prolapse

Outcome measures

Primary outcome

The primary outcome of this study is the long-term disease specific quality of life, measured using the Dutch validated version of the Urinary Distress Inventory.

Secondary outcome

Secondary outcomes will be patient*s subjective satisfaction, general quality of life, sexual functioning, subjective recurrence, objective recurrence using the POP-Q classification, type and number of re-interventions and complications on the long term.

Study description

Background summary

It has been estimated that one in nine women will undergo a hysterectomy during life. Up to 10% of these women will subsequently need surgical repair for vaginal vault prolapse. Sacrocolpopexy is a generally applied treatment, which can be performed by laparoscopy or by laparotomy. After the laparoscopic abdominal sacrocolpopexy had been reported, this procedure has gained popularity. We performed a randomised controlled trial (RCT) comparing laparoscopic sacrocolpopexy versus abdominal sacrocolpopexy, with disease specific quality of life after 1 year as primary outcome (SALTO-1 trial, METC 0631, registered as NTR3276). Results have recently been submitted for publication. Studies to evaluate long-term outcome in this patient group are essential for giving consensus regarding optimal surgical treatment. We

therefore propose a long-term follow-up of the SALTO-1 study.

Study objective

To evaluate long-term outcome (3-10 years) in terms of quality of life, subjective and anatomic failure and erosion after laparoscopic versus open abdominal sacrocolpopexy as a treatment for vaginal vault prolapse in patients with a history of hysterectomy.

Study design

Long-term follow-up of a multicentre RCT.

Study burden and risks

Participation in the study entails a one-time questionnaire containing UDI, DDI, IIQ, PIS-Q, PFDI-20 and SF-36, which will take approximately 20 minutes and secondly a single visit to the outpatient clinic of the nearest participating hospital for a gynecological examination using the POP-Q classification. Subjects will not be at any risk of complications during this study. The POP-Q is a non-invasive, safe way to objectify pelvic floor problems. Subjects can however experience some discomfort during the exam. Though this study will not benefit the participators directly, it will increase our knowledge of long-term outcome after laparoscopic versus open abdominal sacrocolpopexy, which is needed to give consensus regarding optimal surgical treatment for vaginal vault prolapse in patients with a history of hysterectomy.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- All patients from the original SALTO trial.
- Willing to participate.

Exclusion criteria

- Deceased patients
- Unwilling to participate.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-07-2017

Enrollment:	74
Type:	Actual

Ethics review

Approved WMO Date:	03-04-2017
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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
CCMO	NL60618.015.17
Other	NTR26500