Subjective and objective outcome after laparoscopic sacrocolpopexy

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON42649

Source
ToetsingOnline

Brief title
SOOS-study

Condition

- Other condition
- Reproductive tract disorders NEC
- Obstetric and gynaecological therapeutic procedures

Synonym
recurrent vaginal prolapse, vaginal vault prolapse

Health condition

(recidief) prolaps

Research involving
Human

Sponsors and support

Primary sponsor: Diakonessenhuis Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Laparoscopic sacrocolpopexy, Mesh, Outcome, Safety

Outcome measures

Primary outcome

Subjective effectiveness of the laparoscopic sacrocolpopexy: by evaluating the

validated questionnaire filled in by the eligible patients.

Secondary outcome

- objective effectiveness bij gynaecological examination

- safety of the procedure by evaluating the per- and postoperative

complications.

- evaluating the actual quality of life, remaining or new urogynaecologic

symptoms and signs 1-11 years postsurgery by a validated questionnaire.

Study description

Background summary

Prolapse is common medical condition for women over 40 years of age, more than 40% of these women has a prolapse [Slieker 2009]. The majority has no symptoms of this condition; however some have severe complaints. In Dutch literature the lifetime risk for prolapse surgery varies between 11-19% [Olsen 1997]. Increase in this lifetime risk is expected, given the increasing expected female age and the importance of good quality of life for the elderly. The first choice of prolapse surgery is by native tissue repair.
However, the incidence of recurrent prolapse and the need for surgical repair, is estimated at 10-30% [Olsen 1997]. In the case of a prolapse recurrence a laparoscopic sacrocolpopexy using Mesh is proven to be a safe and effective choice [Maher 2011]. At short term (<24 months), mesh surgery would have better

anatomical and functional results compared to vaginal mesh therapy [Maher 2011].
At this moment, long-term safety and efficacy is still unknown. A long-term complication of mesh surgery is the risk of exposure, which is estimated to be 4-19% in various studies [NVOG richtlijn prolapse, p98].
This retrospective cohort of 189 women who were operated in the Diakonessenhuis between 2004 and 2014 is an unique population to answer the question whether the laparoscopic sacrocolpopexy is a safe and effective procedure for women with recurrent vaginal prolapse.

Study objective

The objective of the study is to evaluate the subjective and objective effectivity and safety of the laparoscopic sacrocolpopexy of 189 patients who underwent this procedure in the period August 2004 - December 2014 in the Diakonessenhuis Utrecht/Zeist because of their recurrent prolapse.

Study design

The study design is a retrospective cohort study. The population of interest will be determined by identification of the operation declaration code. Several codes are used these passed 10 years all codes and patients will be sorted out. Eligible patients will be sent a letter in which the study purpose and protocol is explained. An informed consent document will be added and a validated questionnaire as proposed by the Dutch society of obstetrics and gynaecology with a return envelope are enclosed. Participation in the study is voluntary. No benefit is obtained for the eligible patients, unless they consider the outpatient visit as a *check-up*. Patients are asked to fill in the questionnaire and the informed consent form and to return these to the investigator. If they do not wish to participate in the study, they will be asked to return the unfilled questionnaire with a box marked that she does not want to participate in this study.
Several weeks after sending the questionnaire, all patients will be ringed to make an appointment for the outpatient clinic visit to perform the gynaecologic examination. Patients who did not return the questionnaire will be ringed to ask to participate in the study and send back the questionnaire. When informed consent is obtained, an appointment for the outpatient clinic visit to perform the gynaecologic examination.
At the outpatient clinic visit the questionnaire will be checked together with the patient. Questions will be answered. At the gynaecological examination a POP-Q examination will be performed (a standardized method to measure the vaginal prolapse in different compartments using manual examination) and a speculum investigation will be done to investigate the (subclinical) exposures of mesh. This outpatient clinic visit will take approximately 15 minutes in duration. If abnormalities are found with the gynaecologic examination, patients will be referred to the responsible gynaecologist and their general

physician.

Study burden and risks

Patients are asked to fill in and return a validated questionnaire (10 minutes). Also, they will be asked to participate in a outpatient clinic visit to undergo the gynaecological examination (15 minutes).

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

- Patients who underwent a laparoscopic sacrocolpopexy in the period from August 2004 to December 2014 in Diakonessenhuis Utrecht/Zeist

- With good understanding of the Dutch language and willing to complete the validated questionnaire
- Willing to participate in a outpatient clinic visit to undergo a gynaecological examination.

Exclusion criteria

A potential subject who meets not any of the above mentioned inclusion criteria will be excluded from participation in this study: insufficient understanding of Dutch language and not willing to sign informed consent.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2015
Enrollment:	189
Type:	Actual

Ethics review

Approved WMO

Date:	09-02-2016
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL54562.100.15