Pelvic organ prolapse after laparoscopic uterus extirpation: postoperative long-term complication?

Published: 24-02-2017
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The primary objective of this study is to review the incidence of pelvic organ prolapse after laparoscopic hysterectomy compared to vaginal hysterectomy.

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

Summary

ID

NL-OMON42869

Source
ToetsingOnline

Brief title
POP-UP

Condition

- Uterine, pelvic and broad ligament disorders

Synonym
pelvic organ prolapse, prolapse

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: Maatschap Gynaecologie MMC Veldhoven

Intervention

Keyword: laparoscopic hysterectomy, pelvic organ prolapse, vaginal hysterectomy, vaginal vault prolapse

Outcome measures

Primary outcome

- Incidence of anatomic vault prolapse * stage II

- Incidence of symptomatic vault prolapse (* stage II + sensation of a bulge)

- Incidence of asymptomatic and treated vault prolapse (both conservative and

surgical)

Same for prolapse in anterior and posterior compartment.

Secondary outcome

Secondary study outcome

- Incidence of conservative treatment for POP: pelvic floor exercise, vaginal

pessary

- Incidence of POP surgery: pelvic floor repair (anterior repair, posterior

repair, vaginal vault lift by sacrospinous fixation or sacral colpopexy)

- POP symptoms using PFDI-20 questionnaire (Pelvic Floor Distress Inventory)

- POP-Q values

Parameters:

- Age

- Body Mass Index

- Type of hysterectomy

- Indication for hysterectomy

- Obstetric history (parity, macrosomia, age at first delivery)

Study description

Background summary

Hysterectomy in general is a proven risk factor for pelvic organ prolapse (POP), which can seriously discomfort women at any age and often results in surgical repair. Especially vaginal hysterectomy (VH) results in a high number of POPs, which is probably due to the relatively large amount of POP problems as indication for this type of surgery. Long-term studies for pelvic organ prolapse after the recently added laparoscopic approach have not yet been performed. Because the uterosacral ligaments have an important function for the level one support of the pelvic floor and are not harmed during laparoscopy, we believe that laparoscopic hysterectomy (LH) might result in less long-term POP problems compared to VH, when performed for the same, benign indication.

Study objective

The primary objective of this study is to review the incidence of pelvic organ prolapse after laparoscopic hysterectomy compared to vaginal hysterectomy.

Study design

A cross-sectional cohort study will be performed of patients who underwent laparoscopic or vaginal hysterectomy in a single center in the period of 1996 to 2004. The following items will be examined: prolapse treatment (both conservative and surgical), current pelvic floor complaints and observed POP on POP-examination. Therefore, a questionnaire (PFDI-20) and an invitation will be sent for the outpatient study clinic for a one-time pelvic floor exam using the POP-Q.

Study burden and risks

Participation in the study entails a one-time questionnaire using the PFDI-20 scale and questions about other important variables (baseline characteristics, indication for hysterectomy, history of prolapse treatment, obstetric history) which will take approximately 15 minutes and secondly a single visit to our outpatient study department for a gynecological exam using the POP-Q. 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 the long-term risk of hysterectomy on the pelvic floor. It will eventually improve

risk-assessment, counseling and possibly also treatment of patients in the future.

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

- Women with laparoscopic or vaginal hysterectomy between 1996-2004
- Hysterectomy for benign indication
- Women who are still alive and mobile
- Women who are aged under 80 years
- Women who understand the Dutch language

Exclusion criteria

- Subtotal or abdominal hysterectomy
- Hysterectomy for malignant disease
- Women who have passed away
- Women who are aged 80 years or older
- Women who do not understand the Dutch language

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-03-2017
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO

Date:	24-02-2017
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

ID: 20485
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL60096.015.16
OMON	NL-OMON20485