Cross-sectional study to assess the prevalence of vaginal vault prolapse after laparoscopic hysterectomy as a long-term complication.

No registrations found.

Ethical review	Not applicable
Status	Other
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20485

Source
Nationaal Trial Register

Brief title
POP-UP

Health condition

pelvic organ prolapse, vaginal vault prolapse, prolapse after hysterectomy

bekkenbodemklachten, prolapsklachten na hysterectomie

Sponsors and support

Primary sponsor: Afdeling Gynaecologie
Maxima Medisch Centrum, Veldhoven
Source(s) of monetary or material Support: Self funded / Wetenschapsfonds Maxima Medisch Centrum

Intervention

Outcome measures

Primary outcome

- Incidence of anatomic vault prolapse ¡Ý stage II

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

- Incidence of asymptomatic and treated vault prolapse (conservative and surgical)

Same for prolapse in anterior and posterior compartment

Secondary 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

Study description

Background summary

Rationale: 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. 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.

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

Patients and Methods: A 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. We will use a questionnaire (PFDI-20) and patients will undergo a one-time pelvic floor exam using the POP-Q. The population will exist of women, aged thirty to eighty, who underwent laparoscopic or

vaginal hysterectomy for benign indications between 1996 and 2004 in the Máxima Medical Center (MMC).

Study objective

The primary objective of this study is to review the prevalence of pelvic organ prolapse after laparoscopic hysterectomy compared to vaginal hysterectomy. Because the uterosacral ligaments are the important structure for vault suspension after hysterectomy and are not harmed during laparoscopy, we hypothesize that laparoscopic hysterectomy results in less long-term prolapses compared to vaginal hysterectomy

Study design

Both the questionnaire and POP-Q exam will take place before end of the study.

Intervention

- Questionnaire: PFDI-20 (pelvic floor distress inventory), validated in Dutch population. This questionnaire entails questions on pelvic floor problems and/or discomfort within the last three months. Details on micturition, defecation and other prolapse symptoms are addressed.

- Physical examination: POP-Q pelvic organ prolapse quantification. This is a validated, non-invasive, safe way to objectify pelvic organ prolapse during pelvic floor exam.

Contacts

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Eligibility criteria

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 non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-02-2017
Enrollment:	900
Type:	Unknown

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 42869
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5967
NTR-old	NTR6333
CCMO	NL60096.015.16
OMON	NL-OMON42869

Study results