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

Gepubliceerd: 09-11-2016 Laatst bijgewerkt: 15-05-2024

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...

Ethische beoordeling	Niet van toepassing
Status	Anders
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20485

Bron
Nationaal Trial Register

Verkorte titel
POP-UP

Aandoening

pelvic organ prolapse, vaginal vault prolapse, prolapse after hysterectomy

bekkenbodemklachten, prolapsklachten na hysterectomie

Ondersteuning

Primaire sponsor: Afdeling Gynaecologie
Maxima Medisch Centrum, Veldhoven
Overige ondersteuning: Self funded / Wetenschapsfonds Maxima Medisch Centrum

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- 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

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

- 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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	01-02-2017
Aantal proefpersonen:	900
Type:	Onbekend

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 42869
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten