Pelvic organ mobility after treatment for uterine descent

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

Summary

ID

NL-OMON41071

Source
ToetsingOnline

Brief title
Mobility after treatment

Condition

- Uterine, pelvic and broad ligament disorders
- Obstetric and gynaecological therapeutic procedures

Synonym
prolapse, uterine descent

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: geen sponsor / geen subsidie

Intervention

Keyword: Mobility, MRI, Pelvic organ, Uterine descent

Outcome measures

Primary outcome

Primary outcome is the mobility of the pelvic organs (displacement of the bladder, vagina, cervix or apex and rectum) between three commonly performed treatment options for uterine descent.

Secondary outcome

Secondary outcome is the correlation between the clinical results (MRI findings, POP-Q assessment) and symptoms of POP.

Study description

Background summary

Pelvic organ prolapse (POP) is a common health problem. Three different surgical techniques for treatment of uterine descent are vaginal hysterectomy, vaginal sacrospinous hysteropexy and laparoscopic sacrohysteropexy. When looking at de novo or recurrence of prolapse after surgery for descensus uteri, the high rate of anterior vaginal wall prolapse after sacrospinous hysteropexy is prominent. Studying the anatomical and functional differences after surgery is of interest, because it might give a possible explanation of the high rate of de novo or recurrence anterior vaginal wall prolapse after vaginal sacrospinous hysteropexy. Furthermore, the correlation between displacement of pelvic organs (assessed by dynamic MRI), symptoms and POP-Q has not been determined yet.

Study objective

The primary objective is to assess the differences in mobility of pelvic organs between three commonly performed treatment options for uterine descent (vaginal hysterectomy, vaginal sacrospinous hysteropexy and laparoscopic sacrohysteropexy). The secondary objective is to determine the correlation between the clinical results (MRI findings, POP-Q assessment) and symptoms of

POP.

Study design

Pilot cross-sectional study at one time point (6 months postoperatively: MRI, gynecological examination, questionnaire)

Study burden and risks

Participating in this study is without risks for the participants. The burden for the participants consists of the time it takes to fill in the questionnaire, go to the hospital and undergo a MRI scan. One extra visit to the hospital will be necessary. The use of vaginal and rectal contrast at MRI scanning might cause discomfort for the participants. There is no direct benefit for the participants.

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 recently underwent a vaginal hysterectomy, vaginal sacrospinous hysteropexy and laparoscopic sacrohysteropexy as a primary treatment for uterine descent (without surgery for prolapse or hysterectomy in the past)

Exclusion criteria

Factors that will preclude MRI interpretation (e.g. prosthetic hip)
Contra-indications for MRI (e.g. claustrophobia, metal clips)
Not physically able to maintain Valsalva maneuvre for at least 10 seconds (e.g. pulmonary problems)
Neurological disease affecting the pelvic floor
Previous pelvic floor surgery

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):	03-11-2014
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	19-08-2014
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	22-09-2014
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

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	NL49444.075.14