The sacrospinous hysteropexy; a cross-sectional cohort study of 75 cases in a Dutch teaching hospital.

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1. To assess anatomical outcome before and after sacrospinous hysteropexy by a POP-Q and to compare with anatomical situation before surgery.2. To assess urogenital and defecatory symptoms, sexual disfunction and quality of life after sacrospinous...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Obstetric and gynaecological therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON34617

Source
ToetsingOnline

Brief title
-

Condition

- Obstetric and gynaecological therapeutic procedures

Synonym
descensus uteri, prolapse

Research involving
Human

Sponsors and support

Primary sponsor: Obstetrie & Gynaecologie
Source(s) of monetary or material Support: geen financiering

Intervention

Keyword: anatomical outcome, hysteropexy, subjective outcome, uterovaginal prolapse

Outcome measures

Primary outcome

Anatomical outcome will be assessed with a POP-Q assessment and will be compared with the POP-Q assessment before surgery.

Secondary outcome

- Quality of life after surgery will be assessed by using a standardized general quality of life questionnaire (SF-36) and subjective outcome after surgery by validated disease-specific Qol questionnaires (Urogenital Disease Inventory, Defecation Distress Inventory and Incontinence Impact Questionnaire).
- Sexual functioning after surgery will be assessed using the PISQ-12 translated in Dutch and selected items from the *Vragenlijst Seksuele Disfuncties*.

Study description

Background summary

Among aging women, uterovaginal prolapse is a common health problem. About 40% of parous woman have uterovaginal prolapse, and one in every 10 women will have a uterovaginal prolapse that requires surgery. Unfortunately, the prolapse recurs in 29% of women, with the need for a second surgical intervention.

Vaginal hysterectomy, combined with other prolapse surgery if necessary, is currently the leading treatment in the Netherlands, for patients with symptomatic uterovaginal prolapse. However, it has been suggested that hysterectomy may cause an increased risk for bladder dysfunction and stress incontinence, vaginal vault prolapse and/or enterocele and defaecatory

symptoms. Moreover, conceptually vaginal hysterectomy is not the logical first choice in treating women with symptomatic uterovaginal prolapse, and data from literature support this.
Many other procedures have been described, including vaginal, abdominal and laparoscopic approaches. If one chooses a vaginal procedure to correct uterovaginal prolapse, one can choose to retain and suspend the prolapsed uterus rather than removing it. Women have several reasons for wanting to preserve the uterus, such as retaining fertility and maintaining their personal identity. Studies comparing vaginal hysterectomy (removing uterus) to sacrospinous hysteropexy (suspending uterus), demonstrated a longer hospital stay, more pain and longer recovery in the hysterectomy group.

Conflicting data about anatomical outcome and patient satisfaction after sacrospinous hysteropexy have appeared in the literature. Several studies have shown the sacrospinous hysteropexy is anatomically effective and safe and most women are highly satisfied about the procedure. Outcome in these studies is mainly assessed in terms of anatomical results, but there is also an evaluation about urogenital symptoms and quality of life with validated questionnaires. Results show that scores on all domains of urogenital symptoms and defecatory symptoms, except for the pain and fecal incontinence domain, improved significantly. Also, quality of life improved on all domains.
However, the only randomised controlled trial study comparing vaginal hysterectomy and sacrospinous hysteropexy showed recurrences after one year in 27% after sacrospinous hysteropexy versus 3% after vaginal hysterectomy.

We will performe a cross-sectional study to evaluate anatomical outcome of sarcospinous hysteropexy and to assess urogenital and defectory symptoms and quality of life, including sexual functioning, after sacrospinous hysteropexy.

Study objective

1. To assess anatomical outcome before and after sacrospinous hysteropexy by a POP-Q and to compare with anatomical situation before surgery.
2. To assess urogenital and defecatory symptoms, sexual disfunction and quality of life after sacrospinous hysteropexy, in women with uterovaginal prolaps.

Study design

The proposed study concerns a cross-sectional single centre cohort study, in Medisch Centrum Leeuwarden. This study is designed to assess quality of life, urogenital en defecatory symptoms, sexual functioning and anatomical outcome, in women with uterovaginal prolaps.
After inclusion, patients will receive validated questionnaires which they can fill in at home. After that, they will come to the hospital and undergo gynecological examination, including a POP-Q test.

Study burden and risks

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Contacts

Public
Selecteer

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Scientific
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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 who underwent a sacrospinous fixation at Medisch Centrum Leeuwarden between April 2008 and October 2009

Exclusion criteria

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Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2010
Enrollment:	75
Type:	Actual

Ethics review

Approved WMO

Date:	04-10-2010
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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	NL32941.099.10