Sacrospinous fixation versus vaginal hysterectomy in treatment of uterine prolapse stage >= 2: a multi-center randomised controlled trial

Published: 18-08-2009
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To investigate the hypothesis that women with uterine prolapse stage 2 or more treated by sacrospinous fixation have equal or lower recurrence rate of prolapse than women with a vaginal hysterectomy.

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

Summary

ID

NL-OMON35140

Source
ToetsingOnline

Brief title
SSF versus vaginal hysterectomy in treatment of uterine prolapse stage >= 2

Condition

- Uterine, pelvic and broad ligament disorders

Synonym
prolapse, uterine descent

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken

Source(s) of monetary or material Support: geen sponsor/subsidie studie

Intervention

Keyword: randomized trial, sacrospinous fixation, uterine descent, vaginal hysterectomy

Outcome measures

Primary outcome

Primary outcome: anatomical outcome and recurrence rate assessed by a

POP-Q-test.

Secondary outcome

Secondary outcomes are subjective improvement on urogenital symptoms and

quality of life (assessed by disease-specific and quality of life

questionnaires), complications following surgery, hospital stay, post-operative

recovery, sexual functioning and costs.

Study description

Background summary

Uterovaginal prolapse is a common health problem, affecting up to 40% of parous women over 50 years old, with significant influence on quality of life. In the Netherlands vaginal hysterectomy is currently the leading treatment method for patients with symptomatic uterovaginal prolapse. Several studies have shown that sacrospinous fixation in case of uterine or vaginal vault prolapse is a safe and effective alternative to vaginal hysterectomy. However to date no large randomised trials with long-term follow-up have been performed to compare efficacy and quality of life between both techniques.

Study objective

To investigate the hypothesis that women with uterine prolapse stage 2 or more treated by sacrospinous fixation have equal or lower recurrence rate of prolapse than women with a vaginal hysterectomy.

Study design

A multi-center, prospective, randomised, non-blinded clinical trial. Evaluation will take place in every center pre-operatively, after 6 weeks, 6 months, 12 months and annually thereafter.

Intervention

Random allocation to sacrospinous fixation or vaginal hysterectomy

Study burden and risks

As we compare two strategies that are already applied in current practice, no additional risks from both procedures are expected. During follow up extra visits to the hospital for gynaecological examination and data obtaining (self-reported questionnaires) will be necessary in both groups.

Contacts

Public
Isala Klinieken

Postbus 10400
8000 GK Zwolle
NL
Scientific
Isala Klinieken

Postbus 10400
8000 GK Zwolle
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

POP-Q stage >=2 uterine descent requiring surgery. Patients with co-existing anterior/ posterior defects or concomitant incontinence surgery (TVT-O) can be included

Exclusion criteria

- Previous pelvic floor or prolapse surgery
- Known malignancy or abnormal cervical smears
- Wish to preserve fertility
- Unwilling to return for follow-up or language barriers
- Presence of immunological / haematological disorders interfering with recovery after surgery
- Abnormal ultrasound findings of uterus or ovaries, or abnormal uterine bleeding.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-11-2009
Enrollment:	198
Type:	Actual

Ethics review

Approved WMO

Date:	18-08-2009
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	07-10-2019
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	NL28669.075.09