Hysteropexy in treatment of uterine prolapse stage >= 2: laparoscopic sacrohysteropexy versus vaginal sacrospinous hysteropexy (LAVA-trial)

Published: 09-07-2013 Last updated: 07-02-2025

To investigate the hypothesis that women with uterine prolapse stage 2 or more treated by laparoscopic sacrohysteropexy will have equal or lower recurrence rate of prolapse compared to women treated by vaginal sacrospinous hysteropexy.

Ethical review Approved WMO **Status** Completed

Health condition type Uterine, pelvic and broad ligament disorders

Study type Interventional

Summary

ID

NL-OMON40293

Source

ToetsingOnline

Brief title

LAVA-trial

Condition

Uterine, pelvic and broad ligament disorders

Synonym

prolapse, uterine descent

Research involving

Human

Sponsors and support

Primary sponsor: Isala Klinieken

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

Intervention

Keyword: Laparoscopic sacrohysteropexy, Randomized trial, Uterine descent, Vaginal sacrospinous hysteropexy

Outcome measures

Primary outcome

Anatomical outcome and recurrence rate assessed by the POP-Q test at 1 and 5 years follow-up. Recurrence rate is defined as uterine prolapse >= 2 with symptoms.

Secondary outcome

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 and sexual functioning, costs-effectiveness.

Study description

Background summary

Uterovaginal prolapse is a common health problem affecting up to 40% of parous women over 50 years old. The lifetime risk of surgery for pelvic organ prolapse by the age of 85 years is 19%. Pelvic organ prolapse has significant negative effects on a woman*s quality of life. In the Netherlands, vaginal hysterectomy is the leading treatment method for patients with symptomatic uterovaginal prolapse. Several studies have shown that vaginal sacrospinous hysteropexy and laparoscopic sacrohysteropexy are safe and effective alternatives in treating uterine descent. It is unclear to date which of these techniques leads to the best operative result and the highest patient satisfaction.

Study objective

To investigate the hypothesis that women with uterine prolapse stage 2 or more

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treated by laparoscopic sacrohysteropexy will have equal or lower recurrence rate of prolapse compared to women treated by vaginal sacrospinous hysteropexy.

Study design

A multi-center, prospective, randomised, non-blinded clinical trial. Evaluation will take place in every center pre-operatively, and 6 weeks, 6 months, 12 months and annually thereafter till 60 months after surgery.

Intervention

Random allocation to vaginal sacrospinous hysteropexy or laparoscopic sacrohysteropexy.

Study burden and risks

As we compare two strategies that are already applied in current practice, no additional risks from both procedures are expected. Buttock pain occurs in 10-15% of patients after vaginal sacrospinous fixation, but resolves spontaneously. In laparoscopic sacrohysteropexy, there is a risk of mesh-erosion.

Extra visits to the hospital for follow-up and data obtaining will be necessary for both groups.

Contacts

Public

Isala Klinieken

Dr van Heesweg 2 Zwolle 8025 AB NL

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

Uterine descent POP-Q stage >= 2 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

Wish to preserve fertility

Known malignancy or abnormal cervical smears

Unwilling to return for follow-up or language barriers

Presence of immunological/haematological disorders interfering with recovery after surgery

Contraindications for laparoscopic surgery (ileus, risk of severe adhesions)

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: Completed

Start date (anticipated): 02-08-2013

Enrollment: 104

Type: Actual

Ethics review

Approved WMO

Date: 11-07-2013

Application type: First submission

Review commission: CCMO: Centrale Commissie Mensgebonden Onderzoek (Den

Haag)

Approved WMO

Date: 11-07-2013

Application type: First submission

Review commission: METC Isala Klinieken (Zwolle)

Approved WMO

Date: 09-12-2013

Application type: Amendment

Review commission: CCMO: Centrale Commissie Mensgebonden Onderzoek (Den

Haag)

Approved WMO

Date: 09-12-2013

Application type: Amendment

Review commission: METC Isala Klinieken (Zwolle)

Approved WMO

Date: 04-03-2014

Application type: Amendment

Review commission: CCMO: Centrale Commissie Mensgebonden Onderzoek (Den

Haag)

Approved WMO

Date: 04-03-2014

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 NL43801.075.13