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

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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

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

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

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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