The LAVA-trial: hysteropexy in treatment of uterine prolape stage ≥ 2: laparoscopic sacrohysteropexy versus vaginal sacrospinous hysteropexy

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24294

Source
Nationaal Trial Register

Brief title
LAVA trial

Health condition

uterine prolapse, vaginal sacrospinous hysteropexy, laparoscopic sacrohysteropexy

Sponsors and support

Primary sponsor: Isala Klinieken Zwolle
Source(s) of monetary or material Support: Isala Klinieken Zwolle

Intervention

Outcome measures

Primary outcome

The composite primary study outcome of this study is surgical success at 1 and 5 years

follow-up. Surgical success is defined as 1) position of the cervix at or above the mid-vagina (C < -TVL/2), 2) no bothersome bulging/protrusion symptoms and 3) no repeat surgery or pessary use for recurrent apical prolapse. Failure in one or more of these three areas constitute a failure.

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, sexual functioning and costs-effectiveness.

Study description

Background summary

Randomized controlled trial to study the effects of laparoscopic sacrohysteropexy versus vaginal sacrospinous hysteropexy, on prolapse recurrence, quality of life, complications, hospital stay, post-operative recovery, sexual functioning and costs.

Study objective

In the treatment of uterine prolapse stage 2 or higher, the laparoscopic sacrohysteropexy will be equal or more successful in correction of uterine prolapse (lower recurrence rate) as compared to vaginal sacrospinous fixation.

Study design

Evaluation will take place pre-operatively, and 6 weeks, 6 months, 12 months and annually thereafter till 60 months after surgery.

Intervention

The LAVA-trial compares the vaginal sacrospinous hysteropexy to the laparoscopic sacrohysteropexy in the treatment of uterine descent. In the vaginal sacrospinous hysteropexy, the uterus is suspended to the sacrospinous ligaments with permanent sutures. In the laparoscopic sacrohysteropexy, the uterus is elevated by attaching the cervix to the sacral promontory, using a mesh. Both procedures are used in correcting uterine descent. Eligible women will be randomly allocated to receive either a laparoscopic sacrohysteropexy or a vaginal sacrospinous hysteropexy. The vaginal procedure can be performed under general or spinal anaesthesia, according to the preference of patient and anaesthesiologist. The laparoscopic procedure will be performed under general anaesthesia. Post-operative follow-up will take place after 6 weeks, 6 months, 12 months and annually thereafter until 5 years. Patients will undergo a standard gynecological examination (including a POP-Q

examination) and fill in questionnaires.

Contacts

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Eligibility criteria

Inclusion criteria

Women with uterine prolapse stage ≥ 2 requiring surgical treatment

Exclusion criteria

1. Contraindications of laparoscopic surgery;

2. Previous pelvic floor or prolapse surgery;

3. Known malignancy or abnormal cervical smears;

4. Unwilling to return for follow-up or language barriers;

5. Wish to preserve fertility;

6. Presence of immunological/haematological disorders interfering with recovery after surgery;

7. Abnormal ultrasound findings of uterus or ovaries, or abnormal uterine bleeding.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2013
Enrollment:	124
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	09-06-2013
Application type:	First submission

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
NTR-new	NL3841
NTR-old	NTR4029
Other	METc Zwolle : 13.0320
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A