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

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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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24294

Bron
Nationaal Trial Register

Verkorte titel
LAVA trial

Aandoening

uterine prolapse, vaginal sacrospinous hysteropexy, laparoscopic sacrohysteropexy

Ondersteuning

Primaire sponsor: Isala Klinieken Zwolle
Overige ondersteuning: Isala Klinieken Zwolle

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Women with uterine prolapse stage ≥ 2 requiring surgical treatment

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2013
Aantal proefpersonen:	124
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	09-06-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3841
NTR-old	NTR4029
Ander register	METc Zwolle : 13.0320
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A