SAVE U -trial: Sacrospinous fixation versus vaginal hysterectomy in treatment of a uterine prolapse stage ≥ 2: a multi-center randomised controlled trial.

No registrations found.

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

Summary

ID

NL-OMON26877

Source
Nationaal Trial Register

Brief title
SAVE U

Health condition

- uterine descent, vaginal hysterectomy, sacrospinous fixation

- descensus uteri, vaginale hysterectomie,
sacrospinale fixatie

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Surgical failure, defined as recurrence of prolapse POP-Q stage 2 of the middle compartment and prolapse complaints and/or redo surgery.

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 and sexual functioning.

Study description

Background summary

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

Study objective

In the treatment of a uterine prolapse stage 2 or higher sacrospinous fixation will result in equal or lower recurrence rate of prolapse than a vaginal hysterectomy.

Study design

Pre-operative, 6 weeks, 6, 12, 24, 36, 48 and 60 months postoperative.

Intervention

Random allocation to sacrospinous fixation or vaginal hysterectomy.

Contacts

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Eligibility criteria

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 too.

Exclusion criteria

1. Previous pelvic floor or prolapse surgery;

2. Known malignancy or abnormal cervical smears;

3. Wish to preserve fertility;

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

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

6. 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):	01-08-2009
Enrollment:	208
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	18-06-2009
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	NL1755

Register	ID
NTR-old	NTR1866
Other	METC Zwolle : METC 09.0652
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A