

Electrosurgical bipolar vessel sealing using LigaSure versus conventional clamping and suturing for vaginal hysterectomy: a randomized controlled trial

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To randomly compare the effects of vessel sealing LigaSure on the operative parameters, post-operative pain and recovery and post-operative function of the pelvic floor in vaginal hysterectomy,

Ethical review	Approved WMO
Status	Pending
Health condition type	Uterine, pelvic and broad ligament disorders
Study type	Interventional

Summary

ID

NL-OMON33905

Source

ToetsingOnline

Brief title

LigaSure vaginal hysterectomy

Condition

- Uterine, pelvic and broad ligament disorders
- Obstetric and gynaecological therapeutic procedures

Synonym

removal of the uterus through vagina, vaginal hysterectomy

Research involving

Human

Sponsors and support

Primary sponsor: H4

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Vaginal hysterectomy, Vessel sealing

Outcome measures

Primary outcome

Pain score post-operatively as measured with the Visual analogue score.

Secondary outcome

Surgery time, blood loss, hospital stay

Limitations in daily functioning the first six weeks after surgery

Pelvic floor function (micturition, defecation, sexual functioning)

Generic quality of life

Costs

Study description

Background summary

Hysterectomy is a commonly performed operation. The operation can be performed abdominally as well as vaginally. Recent investigation has shown lower post-operative painscores and faster recovery till normal daily activities after abdominal hysterectomy with the help of LigaSure technique. This advantage might also be there after vaginal hysterectomy. Furtheron there are clues that through traction on the pelvic nerves vaginal hysterectomy might increase the risk of pelvic floor dysfunction compared to abdominal hysterectomy. Our hypothesis is that operation with LigaSure might diminish this risk through less lateral nerve damage and less traction on the nerves.

Study objective

To randomly compare the effects of vessel sealing LigaSure on the operative parameters, post-operative pain and recovery and post-operative function of the pelvic floor in vaginal hysterectomy,

Study design

Randomised controlled trial

Intervention

One group of patients undergo vaginal hysterectomy with the help of LigaSure device. The other patients undergo vaginal hysterectomy according to the conventional technique.

Study burden and risks

Patients are asked to fill out a questionnaire before operation, six weeks and six months after operation. And a daily questionnaire till two weeks after operation. This takes mostly 2 hours time spread in 6 months. There are no risks at operating with LigaSure technique.

Contacts

Public

Selecteer

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Scientific

Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

women, age above 18 years, undergoing vaginal hysterectomy for benign diseases

Exclusion criteria

Patients undergoing vaginal hysterectomy for treatment of symptomatic genital prolapse.

Patients undergoing concomitant surgical procedures

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-04-2009
Enrollment:	100
Type:	Anticipated

Medical products/devices used

Generic name:	Using Vessel sealing;LigaSure;during vaginal hysterectomy
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Registration: Yes - CE intended use

Ethics review

Approved WMO

Application type: First submission

Review commission: METC Amsterdam UMC

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	NL26335.018.08