Hemostasis with vesselsealinstrument compared to conventional bipolar coagulation in laparascopic hysterectomy and/or salpingo-ooforectomy. a randomised trial

No registrations found.

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

Summary

ID

NL-OMON26591

Source
NTR

Brief title
N/A

Health condition

vesselseal, laparoscopy, hysterectomy, oophorectomy

Sponsors and support

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Source(s) of monetary or material Support: Tyco supported the website

Intervention

Outcome measures

Primary outcome

1. Operating time;
2. Intraoperative bloodloss

Secondary outcome

1. Hemoglobin drop;
2. User satisfaction;
3. Costs;
4. Quality of life (SF36)

Study description

Background summary

Laparoscopic hysterectomy and/or oophorectomy undergo a slow but steady implementation in the Netherlands. Hemostasis in laparoscopic surgery is sometimes problematic with the conventional methods, such as bipolar coagulation. Since recently a new vesselsela technique is commercially available. The objective of the technique is to close the vessel quicker and more effective. This should result in shorter operating time and less bloodloss. This hypothesis is tested in the current study.

Study objective

The vesselseal instrument results in shorter operating time and less intraoperative bloodloss than the conventional bipolar coagulation in patients undergoing laparoscopic hysterectomy and/or salpingo-oophorectomy

Intervention

Hemostasis with vesselseal technique

Contacts

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Eligibility criteria

Inclusion criteria

1. Laparoscopic hysterectomy;
2. Laparoscopic oophorectomy

Exclusion criteria

1. Ovarian or cervical cancer;
2. Uterus size > 20 weeks pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2007
Enrollment:	144
Type:	Anticipated

Ethics review

Positive opinion

Date:	01-05-2007
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	NL939
NTR-old	NTR964
Other	:
ISRCTN	ISRCTN80747160

Study results

Summary results
Articles on (laparoscopic) hysterectomy Brölmann

Brölmann HAM. Laparoscopische assistentie bij hysterectomie; modus of mode. Ned T Obstetrie en Gynaecologie 1995;108:365 – 366
HAM Brölmann, S de Blok, IMHE Buijs. Van kijkbuis naar doebuis; de gevolgen voor de hysterectomie. Ned T Obstet Gynaecol 1996;109:313 – 316
Derksen JGM, Brölmann HAM, Wiegerinck, Vader HL, Heintz APM. The effect of hysterectomy and endometrial ablation on follicle stimulating hormone (FSH) levels up to 1 year after surgery. Maturitas 1998;29:133 – 138
HAM Brölmann, MY Bongers. Resultaten van laparoscopisch geassisteerde vaginale hysterectomieen in het Ikazia Ziekenhuis te Rotterdam, 1993-1997 (ingezonden brief). Ned T Geneesk 1998;142:2431
HAM Brölmann. Wel of niet sluiten van het peritoneum na een vaginale hysterectomie. NTOG 2000;113:231 - 232
HAM Brölmann. Vasopressin during abdominal hysterectomy reduced bloodloss by 40 % (commentary). J Evidence Based Obstetrics and Gynecology 2002;2:78-9
HAM Brölmann, MY Bongers, GL Bremer, PCM van der Salm. A randomised comparison and economic evaluation in laparoscopic assisted hysterectomy and abdomminal hysterectomy. (correspondence). Brit J Obstet Gynaecol 2002;109:1427-28.
Brölmann HAM. Laparoscpic hysterectomy had a higher rate of major complications than abdominal hysterectomy (comment). Evidence based Obstet Gynecol 2004;6:122-24.
Kluivers KB, Bongers MY, Mol BWI, Bremer GL, Weemhoff m, Brölmann HAM, Withagen MIJ, Vierhout ME. Pevic organ function in randomised laparoscopic and abdominal hysterectomy patients. Poster ESGE Annual Congress, Strassbourg, October 2006