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Haemostasis with vessel seal instrument compared to conventional bipolar coagulation in laparascopic hysterectomy and/or salpingo-ooforectomy: a randomised trial

Submission date
30/05/2007

Recruitment status
No longer recruiting

Registration date
30/05/2007

Overall study status
Completed

Last Edited
19/10/2021

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.studies-obsgyn.nl/vesselseal/

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NL939 (NTR964)

Study information

Scientific Title
Haemostasis with vessel seal instrument compared to conventional bipolar coagulation in laparascopic hysterectomy and/or salpingo-ooforectomy: a randomised trial

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

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised, multicentre, active controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Vessel seal, hysterectomy, laparoscopy, oophorectomy

Interventions
Hemostasis with vessel seal technique versus conventional technique.

Intervention Type
Procedure/Surgery

Phase

Not Specified

Primary outcome measure
1. Operating time
2. Intraoperative bloodloss

Secondary outcome measures
1. Haemoglobin drop
2. User satisfaction
3. Costs
4. Quality of life, measured using the 36-item Short Form health survey (SF36)

Overall study start date
01/01/2007

Completion date
01/01/2008

Eligibility

Key inclusion criteria
1. Laparoscopic hysterectomy
2. Laparoscopic oophorectomy

Participant type(s)
Patient

Age group
Not Specified

Sex
Female

Target number of participants
144

Key exclusion criteria
1. Ovarian or cervical cancer
2. Uterus size greater than 20 weeks pregnancy

Date of first enrolment
01/01/2007

Date of final enrolment
01/01/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Vrije University Medical Centre (VUMC)
Amsterdam
Netherlands
-

Sponsor information

Organisation
Vrije University Medical Centre (VUMC) (The Netherlands)

Sponsor details
Department of Obstetrics and Gynaecology
Division of Reproductive Medicine
P.O. Box 7057
Amsterdam
Netherlands
1007 MB

Sponsor type
Hospital/treatment centre

Website
http://www.vumc.nl/english/#http://www.vumc.nl/english/

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		06/09/2011	19/10/2021	Yes	No