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

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
30/05/2007		☐ Protocol		
Registration date 30/05/2007	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	[] Individual participant data		
19/10/2021	Surgerv			

## 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

Dr A.M. BrÖlmann

## Contact details

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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

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# 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