

# Randomised controlled trial of salpingostomy versus salpingectomy for tubal pregnancy, the impact of future fertility

<b>Submission date</b> 30/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/07/2015	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Study website

<http://www.esepstudy.nl>

## Contact information

### Type(s)

Scientific

### Contact name

Mrs P J Hajenius

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N0116151801

## **Study information**

### **Scientific Title**

Randomised controlled trial of salpingostomy versus salpingectomy for tubal pregnancy, the impact of future fertility

### **Acronym**

ESEP study - European Surgery in Ectopic Pregnancy

### **Study objectives**

Whether the potential advantage of salpingostomy (opening the fallopian tube to remove pregnancy) i.e. better fertility prognosis as compared to salpingectomy (removing the fallopian tube with the pregnancy), outweighs the potential disadvantages of this treatment i.e. persistent trophoblast and an increased risk for ectopic pregnancy.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Ethics approval received from the local medical ethics committee

### **Study design**

Randomised active-controlled parallel-group trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

### **Health condition(s) or problem(s) studied**

Tubal pregnancy

### **Interventions**

Salpingostomy versus salpingectomy.

### **Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

Time to occurrence of a spontaneous intra uterine pregnancy.

**Secondary outcome measures**

Persistent trophoblast and repeat ectopic pregnancy. A cost-effectiveness analysis will be performed.

**Overall study start date**

01/10/2004

**Completion date**

01/01/2010

**Eligibility**

**Key inclusion criteria**

Women with tubal pregnancy and a healthy contra-lateral tube.

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

450

**Key exclusion criteria**

1. Aged less than 18 years
2. Shock
3. Pregnant after In Vitro Fertilisation and Embryo Transfer (IVF-ET)
4. Known tubal pathology
5. No fertility wish

**Date of first enrolment**

01/10/2004

**Date of final enrolment**

01/01/2010

**Locations**

**Countries of recruitment**

Netherlands

Sweden

United Kingdom

**Study participating centre**

**Academic Medical Center**

Amsterdam

Netherlands

1100 DE

## **Sponsor information**

**Organisation**

European Surgery in Ectopic Pregnancy Study Group

**Sponsor details**

PO Box 22700

Academic Medical Center

University of Amsterdam

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**Sponsor type**

University/education

**Website**

<http://www.amc.nl>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

King's College Hospital NHS Trust R&D Consortium (UK)

**Funder Name**

NHS R&D support funding (UK)

**Funder Name**

Netherlands Organisation for Health Research and Development

**Alternative Name(s)**

Netherlands Organisation for Health Research and Development

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

Netherlands

## 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?
<a href="#">Protocol article</a>	protocol	26/06/2008		Yes	No
<a href="#">Results article</a>	results	26/04/2014		Yes	No
<a href="#">Results article</a>	results	01/09/2015		Yes	No