

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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mrs P J Hajenius

Contact details

Department of Obstetrics and Gynaecology
Academic Medical Center
University of Amsterdam
P.O. Box 22700
Amsterdam
Netherlands
1100 DE
+31 (0)20 5663654
esep@amc.uva.nl

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Tubal pregnancy

Interventions

Salpingostomy versus salpingectomy.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Time to occurrence of a spontaneous intra uterine pregnancy.

Key secondary outcome(s)

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

Completion date

01/01/2010

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

United Kingdom

Netherlands

Sweden

Study participating centre

Academic Medical Center

Amsterdam

Netherlands

1100 DE

Sponsor information

Organisation

European Surgery in Ectopic Pregnancy Study Group

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

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	results	26/04/2014		Yes	No
Results article	results	01/09/2015		Yes	No
Protocol article	protocol	26/06/2008		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes