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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

Registration date
30/09/2005

Overall study status
Completed

Last Edited
17/07/2015

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

Primary study design
Interventional

Study design
Randomised active-controlled parallel-group trial

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