The influence of ultrasound contrast for fertility investigation on spontaneous pregnancy

Submission date	Recruitment status No longer recruiting	Prospectively registered		
15/08/2008		☐ Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
26/09/2008		[X] Results		
Last Edited	Condition category	[] Individual participant data		
27/01/2009	Pregnancy and Childbirth			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

The influence of hysterosalpingo contrast sonography (HyCoSy) on spontaneous pregnancy

Study objectives

At our fertility centre, there was a clinical impression that patients who underwent a hysterosalpingo contrast sonography (HyCoSy) often attained spontaneous pregnancy. A second

impression was that the conception occurred shortly after the HyCoSy. A retrospective analysis demonstrated that 50 patients out of 350 (15%) who underwent HyCoSy conceived within a 6 month period. The expected conception rate among patients who did not undergo a HyCoSy for various reasons was estimated to be 5%. Based on this background data a prospective randomised controlled study was initiated at our clinic. The aim of the study was to test whether the use of contrast sonography could enhance the chance of spontaneous clinical pregnancy in women undergoing infertility work-up.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of Medical Faculty, University of Gothenburg. Date of approval: 17/12/2001 (ref: S532-01)

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Subfertility (both male and female)

Interventions

Participant recruitment took place at the Reproductive Unit of the Sahlgrenska University Hospital. Randomisation to the two study arms was carried out in blocks of 40, with stratification for age.

Intervention arm: Vaginal contrast sonography for tubal testing on enrolment in the study Control arm (delayed intervention): Vaginal contrast sonography for tubal testing after 6 months from the day of enrolment in the study

The participants were followed up for 6 months to check for intrauterine pregnancy.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Clinical pregnancy defined as a sonographically visible foetal sac, detected within 6 months from randomisation.

Key secondary outcome(s))

- 1. Live birth
- 2. Miscarriage
- 3. Ectopic pregnancy

Completion date

31/05/2006

Eligibility

Key inclusion criteria

Couples with at least 1 year of infertility who were scheduled for a consultation, including a HyCoSy.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Αll

Key exclusion criteria

- 1. Female age >=40 years
- 2. Severe male infertility (concentration <20 million/ml in the ejaculate or <1 million motile sperms in a swim-up preparation)
- 3. Severe tubal pathology and suspected anovulation (menstrual period longer than 35 days)

Date of first enrolment

01/12/2001

Date of final enrolment

31/05/2006

Locations

Countries of recruitment

Sweden

Study participating centre Department of Obstetrics and Gynaecology

Kungälv Sweden

442 83

Sponsor information

Organisation

University of Gothenburg (Sweden)

ROR

https://ror.org/01tm6cn81

Funder(s)

Funder type

University/education

Funder Name

University of Gothenburg, Sahlgrenska University hospital (Sweden) (ref: LUA/ALF 7094)

Funder Name

Medical Society of Gothenburg (Sweden)

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	01/05/2009		Yes	No