ISRCTN20715945 https://doi.org/10.1186/ISRCTN20715945

The influence of ultrasound contrast for fertility investigation on spontaneous pregnancy

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
1. Live birth
2. Miscarriage
3. Ectopic pregnancy

Overall study start date
01/12/2001

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

Age group
Adult

Sex
Both

Target number of participants
330

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
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Sponsor information

Organisation
University of Gothenburg (Sweden)

Sponsor details
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Sponsor type
University/education

Website
http://www.gu.se/english

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

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	results	01/05/2009		Yes	No