

# The influence of ultrasound contrast for fertility investigation on spontaneous pregnancy

<b>Submission date</b> 15/08/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 26/09/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 27/01/2009	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

**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  $\geq 40$  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)

## Sponsor details

c/o Dr Annika Strandell

Department of Obstetrics and Gynecology

Sahlgrenska University Hospital

Göteborg

Sweden

413 45

## 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?
<a href="#">Results article</a>	results	01/05/2009		Yes	No