

Preimplantation genetic screening (PGS) in women of advanced maternal age

Submission date 14/01/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 21/02/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 11/07/2008	Condition category 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

Contact name
Dr Thorir Hardarson

Contact details
Box 5418
Gothenburg
Sweden
40229

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Preimplantation genetic screening in women of advanced maternal age (AMA) decreased clinical pregnancy rate: a randomised controlled trial

Study objectives

The aim of this randomised study was to investigate whether preimplantation genetic screening (PGS) of embryos on day three would increase the clinical pregnancy rate per randomised patient after in vitro fertilisation (IVF) in women of advanced reproductive maternal age (greater than 38 years).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from Goteborg University Ethics Committee, The Sahlgrenska Academy, on the 14th February 2003 (ref: 610-02).

Study design

An interventional prospective randomised non-blinded, controlled, two-centre study

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

Preimplantation genetic screening

Interventions

All the patients went through the same (standardised) IVF treatment including ovarian stimulation with hormonal substitution. Follicular aspiration was performed to retrieve oocytes and the male partner provided a sperm sample. Fertilisation was performed by IVF or ICSI following standard techniques. Thereafter embryos were cultured for three days. On day three (day of randomisation) the embryos were scored and allocated into the control or PGS group.

The control group received no further treatment and the patient received their embryo(s) on that day.

In the PGS group one cell was biopsied from each embryo and a technique called FISH (fluorescent in-situ hybridisation) was used to determine the number of seven different chromosomes. Only embryos that showed normal chromosomal setup were transferred.

The results were followed up firstly by a pregnancy test (day 14 a ET), then an ultrasound (if the patient had not reported a spontaneous abortion) after six to seven weeks. Thereafter the patients went on to the regular health care system and we received (or followed up) information of the last outcome, i.e., delivery or not, the number of children born and if there were any malformations (not an end point in the study).

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Clinical pregnancy rate, shown as foetal heart activity per randomised patient, measured six to seven weeks after the transfer of the embryo(s).

Secondary outcome measures

1. Pregnancy rate per transfer, measured two weeks after the transfer of the embryo(s)
2. Rate of implantation, measured six to seven weeks after the transfer of the embryo(s)
3. Spontaneous abortion and delivery, measured by looking at hospital records throughout the nine months after the transfer of the embryo(s)

Overall study start date

01/12/2003

Completion date

30/11/2006

Eligibility**Key inclusion criteria**

1. Couples with infertility of female or male origin
2. Intending to undergo IVF or intracytoplasmic sperm injection (ICSI)
3. Signed a written consent form
4. The age of the woman was over 38 years
5. The couple had to have at least three embryos of good morphological quality (GQE). After an amendment, owing to introduction of SET in Sweden in 2003, only two GQE were required.

Randomisation, using a data program, was performed on day three.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

320

Key exclusion criteria

Previous enrolment.

Date of first enrolment

01/12/2003

Date of final enrolment

30/11/2006

Locations**Countries of recruitment**

Sweden

Study participating centre

Box 5418

Gothenburg

Sweden

40229

Sponsor information**Organisation**

Serono Nordic AB (Sweden)

Sponsor details

Frösundaviks Allé 1

Solna

Sweden

19670

Sponsor type

Industry

ROR

<https://ror.org/01vp49361>

Funder(s)**Funder type**

Industry

Funder Name

Merck Serono Nordic AB (Sweden)

Funder Name

Swedish Research Council (Sweden)

Alternative Name(s)

Swedish Research Council, VR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

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	01/12/2008		Yes	No