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

Submission date	Recruitment status	[_] Prospectively registered
14/01/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/02/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/07/2008	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

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 Commitee, 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

Study type(s)
Treatment

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

Key secondary outcome(s))

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)

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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)

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

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