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Preimplantation genetic screening for aneuploidies in patients with advanced maternal age undergoing in vitro fertilisation

Submission date
12/09/2005

Registration date
12/09/2005

Last Edited
20/10/2008

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Protocol serial number
ZonMw: 945-03-013; NTR84

Study information

Scientific Title

Study objectives
To determine whether in vitro fertilisation (IVF)/intracytoplasmic sperm injection (ICSI) combined with preimplantation genetic screening (PGS) in patients with advanced maternal age, i.e. women between 35 and 41 years of age, is a cost-effective alternative compared to IVF/ICSI without PGS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local medical ethics committee

Study design
Randomised, active controlled, parallel group, double blinded, multicentre trial

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Subfertility, infertility

Interventions
Patients are allocated at random to one of two treatment arms:
1. IVF/ICSI with PGS (selection of embryos based on normal number of studied chromosomes), or
2. IVF/ICSI without PGS (selection of embryos based on morphology).

A maximum of two embryos will be transferred, according to the European Society of Human Reproduction and Embryology (ESHRE)-guidelines. In both treatment arms three treatment-cycles will be offered.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Ongoing pregnancy rate.

Key secondary outcome(s)
1. Time to pregnancy
2. Clinical pregnancy rate
3. Pregnancy outcome
4. Implantation rate

Completion date

01/05/2006

Eligibility

Key inclusion criteria
1. Women between 35 and 41 years of age
2. Undergoing IVF or ICSI

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
Does not comply with the above inclusion criteria

Date of first enrolment
01/05/2003

Date of final enrolment
01/05/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
Center For Reproductive Medicine
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
Academic Medical Center (AMC) (The Netherlands)

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

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	05/07/2007		Yes	No