

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

Submission date 12/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 20/10/2008	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

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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