

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

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

**Contact name**  
Dr Sebastiaan Mastenbroek

**Contact details**  
Center For Reproductive Medicine  
Academic Medical Center  
Meibergdreef 9 (A1-229)  
Amsterdam  
Netherlands  
1105 AZ  
+31 (0)20 566 7524/3090  
S.Mastenbroek@amc.uva.nl

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

# 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

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Screening

### Participant information sheet

### 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 measure**

Ongoing pregnancy rate.

**Secondary outcome measures**

1. Time to pregnancy
2. Clinical pregnancy rate
3. Pregnancy outcome
4. Implantation rate

**Overall study start date**

01/05/2003

**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

**Age group**

Adult

**Sex**

Female

**Target number of participants**

372

**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)

**Sponsor details**  
Postbus 22660  
Amsterdam  
Netherlands  
1100 DD

**Sponsor type**  
Hospital/treatment centre

**Website**  
<http://www.amc.uva.nl/>

**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**

**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	05/07/2007		Yes	No