Preimplantation genetic screening (PGS) for aneuploidies in patients with advanced maternal age undergoing in vitro fertilization.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25213

Source
NTR

Brief title
N/A

Health condition

Subfertility/infertility in women with advanced maternal age.

Sponsors and support

Primary sponsor: Academic Medical Center
Source(s) of monetary or material Support: Netherlands Organisation for Health Research and Development (ZonMw)

Intervention

Outcome measures

Primary outcome

Ongoing pregnancy rate.

Secondary outcome

Time to pregnancy, clinical pregnancy rate, pregnancy outcome, implantation rate.

Study description

Background summary

A double-blind randomized controlled trial is conducted to determine whether IVF/ICSI combined with PGS in patients with advanced maternal age, i.e. women between 35 and 40 years of age, is a cost-effective alternative compared to IVF/ICSI without PGS.
Patients are allocated at random to one of two treatment arms:
IVF/ICSI with PGS (selection of embryos based on normal number of studied chromosomes) or IVF/ICSI without PGS (selection of embryos based on morphology). Primary outcome is ongoing pregnancy. Secondary outcomes are time to pregnancy, clinical pregnancy rate, pregnancy outcome and implantation rate.

Study objective

To determine whether IVF/ICSI combined with 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.

Study design

N/A

Intervention

Patients are allocated at random to one of two treatment arms: IVF/ICSI with PGS (selection of embryos based on normal number of studied chromosomes) or IVF/ICSI without PGS (selection of embryos based on morphology). A maximum of two embryos will be transferred, according to the ESHRE-guidelines. In both treatment arms three treatment-cycles will be offered.

Contacts

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Eligibility criteria

Inclusion criteria

Women between 35 and 41 years of age, undergoing IVF (in vitro fertilization) or ICSI (intracytoplasmatic sperm injection).

Exclusion criteria

N/A

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2003
Enrollment:	372
Type:	Actual

Ethics review

Positive opinion

Date:	15-08-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL56
NTR-old	NTR84
Other	: ZON-MW 945-03-013
ISRCTN	ISRCTN76355836

Study results

Summary results

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