

Preimplantation genetic screening (PGS) through 24-chromosome aneuploidy screening of day 3 embryos in advanced maternal aged patients: a prospective randomised controlled trial

Submission date 10/11/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 20/12/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 20/12/2010	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N°GENERA 201003

Study information

Scientific Title

Preimplantation genetic screening on day 3 embryos using Comparative Genomic Hybridization (CGH)-array in women of advanced maternal age: a prospective randomised controlled trial

Acronym

PGS by CGH-array on day 3 embryos in AMA patients

Study objectives

Patients with advanced maternal age (AMA) (36 - 43 years) have a higher ongoing pregnancy rate after embryo transfer of embryos with a normal chromosomal pattern analysed through 24-chromosome aneuploidy preimplantation genetic screening (PGS) compared with patients who had an embryo transfer without PGS.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The local ethics committee (Clinica Valle Giulia, Rome, Italy) approved on the 20th October 2010

Study design

Prospective randomised double blinded study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Infertility

Interventions

1. Control group: ICSI procedure, day 3 zona pellucida laser assisted drilling without blastomere biopsy and Preimplantation Genetic Screening (PGS), day 5 up to double embryo transfer .

2. Study group: ICSI, one-cell embryo biopsy on day 3 and Preimplantation Genetic Screening with array-CGH, day 5 up to double embryo transfer. Embryos with dubious results will be reanalysed by trophoblast biopsy and array-CGH.

All available supernumerary viable embryos will be cryopreserved by vitrification procedure in both groups.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Ongoing pregnancy rate per embryo transfer (defined as the ratio between the number of ongoing pregnancy greater than 20 weeks gestation and the number of embryo transfer performed)

Secondary outcome measures

1. Embryo transfer rate per started cycle
2. Ongoing implantation rate
3. Miscarriage rate
4. Multiple pregnancy rate
5. Ongoing pregnancy rate per started cycle

Overall study start date

01/11/2010

Completion date

01/11/2011

Eligibility

Key inclusion criteria

1. Female patients aged between 36 and 43 years undergoing an in vitro fertilisation (IVF) /intracytoplasmic sperm injection (ICSI) attempt at the GENERA centre for Reproductive Medicine in Rome
2. History of less than 3 consecutive miscarriages and no more than 2 failed IVF/ICSI cycles
3. Greater than or equal to 6 metaphase II (MII) oocytes retrieved
4. Signed consent form

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

200

Key exclusion criteria

1. Azoospermic male partner
2. Severe male factor infertility defined as ejaculate sperm of less than 1 million sperm/ml
3. Hydrosalpinx
4. Polycystic ovarian syndrome (PCOS)
5. Preimplantation genetic diagnosis (PGD) cycles for monogenic defects and/or chromosomal structural abnormalities
6. Female patients with pathological uterine cavity
7. Number of retrieved MII oocytes below 6
8. Known American Society for Reproductive Medicine (ASRM) Grade III or IV endometriosis
9. Maternal disease that is not clinically stable and known to impact the ability to become pregnant or carry a pregnancy to term
 - 9.1. Lupus
 - 9.2. Chronic liver or kidney disease
 - 9.3. Body mass index (BMI) greater than 30
 - 9.4. Uncontrolled hypertension
 - 9.5. Anti-phospholipid antibody
 - 9.6. Thrombophilia
 - 9.7. Insulin dependent diabetes

Date of first enrolment

01/11/2010

Date of final enrolment

01/11/2011

Locations**Countries of recruitment**

Italy

Study participating centre

GENERA

Rome

Italy

00197

Sponsor information

Organisation

BlueGnome Ltd (UK)

Sponsor details

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Sponsor type

Not defined

ROR

<https://ror.org/027c2yv63>

Funder(s)**Funder type**

Research organisation

Funder Name

GENERA Centre for Reproductive Medicine (Italy)

Funder Name

GENOMA Molecular Genetics Laboratory (Italy)

Funder Name

BlueGnome Ltd (UK)

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