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

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

### Contact name

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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 requset 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 Preimplantaion 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 trofoblast biopsy and array-CGH.

All available supenumerary 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 prergnancy 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