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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	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 20/12/2010	**Overall study status** Completed	
Last Edited 20/12/2010	**Condition category** Pregnancy and Childbirth	

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 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)

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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