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Preimplantation genetic screening (PGS) by array-comparative genomic hybridization (CGH) on day 5 embryos with day 6 fresh transfer in repeated implantation failure (RIF) patients

Submission date
18/11/2011

Recruitment status
No longer recruiting

Registration date
09/12/2011

Overall study status
Completed

Last Edited
12/06/2017

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
In vitro fertilisation (IVF) is a technique to help people with fertility problems to have a baby. During IVF, an egg is removed from the woman's ovaries and fertilised with sperm in a laboratory (intra-cytoplasmic sperm injection [ICSI]). The fertilised egg (embryo) is then returned to the woman's womb to grow and develop. Preimplantation genetic screening (PGS) involves checking the embryos for common chromosome abnormalities. PGS has mainly involved checking a limited number of chromosomes (5-9 chromosomes). Embryos with the correct number of chromosomes are selected for transfer to the woman's womb. However, this test has produced contradictory results that can be explained by technical differences and the limited number of chromosomes assessed. The 24 chromosomes array-comparative genomic hybridization (array-CGH) PGS test involves assessing all 24 chromosomes, which may overcome the technical difficulties that beset earlier PGS studies. Therefore, the aim of this study is to find out whether PGS for all 24 chromosomes by array-CGH increases pregnancy and live birth rates.

Who can participate?
Women aged 36 or younger with a history of more than two failed IVF/ICSI cycles without pregnancy

What does the study involve?
Participants are randomly allocated to undergo ICSI either with or without PGS for all 24 chromosomes by array-CGH. The morphology (shape) of the embryos obtained and the pregnancy and live birth rates in both groups are compared.

What are the possible benefits and risks of participating?
PGS is provided free of charge and may improve the participants’ odds of conceiving. The information obtained from this study may also help to advance the science involved with PGS in IVF. Egg retrieval is a common procedure, but complications can still sometimes occur. There are risks involved with any treatment involving fertility drugs and egg retrieval.

Where is the study run from?
GENOMA Molecular Genetics Laboratory (Italy)

When is the study starting and how long is it expected to run for?
December 2011 to December 2012

Who is funding the study?
1. BlueGnome (UK)
2. GENOMA Molecular Genetics Laboratory (Italy)
3. Genera (Italy)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18112011

Study information

Scientific Title
Preimplantation genetic screening (PGS) by array-comparative genomic hybridization (CGH) on day 5 embryos with day 6 fresh transfer in repeated implantation failure (RIF) patients: a randomised double-blinded study

Study objectives

Patients with repeated implantation failure (RIF) have a higher ongoing pregnancy rate and live birth rate after embryo transfer of embryos with a normal chromosomal pattern analysed by 24 chromosome aneuploidy screeninig (PGS) compared with patients who had an embryo transfer on day 6 without PGS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Local Ethics Committee (Genoma, Rome, Italy), 18/10/2011

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 the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Infertility

Interventions
Control group: ICSI procedure, day 5 Laser Assisted drilling without Preimplantaion Genetic Screening, day 6 embryo transfer

Study group: ICSI and Preimplantation Genetic Screening with array-CGH, embryo biopsy on day 5, day 6 embryo transfer

Intervention Type
Procedure/Surgery

Primary outcome measure
Live birth rate [Time Frame: 1 year after embryo transfer]; pregnancies that arrive to term divided by procedures with an egg retrieval

Secondary outcome measures
1. Ongoing pregnancy rate per embryo transfer [Time Frame: 20 weeks after embryo transfer]. Ongoing pregnancy defined as the presence of a fetal sac. Pregnancy rate per transfer defined as pregnancies divided by patients with a replacement of embryos.

2. Pregnancy rate per retrieval [Time Frame: 20 weeks after embryo transfer]. pregnancy defined as the presence of a fetal sac. Pregnancy rate per retrieval defined as pregnancies divided by patients with an egg retrieval.
3. Ongoing pregnancy rate per started cycle [Time Frame: 20 weeks after embryo transfer]
4. Ongoing implantation rate [Time Frame: 12 weeks after embryo transfer]
5. Number of embryos implanted divided by number of embryos replaced. An embryo implanted is measured as a fetal sac by ultrasound observation.
6. Embryo transfer rate per started cycle

Overall study start date
01/12/2011

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Female patients aged 36 years old or younger undergoing an Intra-cytoplasmic sperm injection (ICSI) attempt at GENERA Clinic in Rome
2. History of more than two failed In vitro fertilisation (IVF)/ICSI cycles; without clinical pregnancy with transfer of at least one good quality embryos per transfer
3 .≥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 < 1million sperm/ml
3. Hydrosalpinx
4. Polycystic ovary syndrome (PCOS)
5. Pre-implantation genetic diagnosis (PGD) cycles [Single Gene Disorders (SGD) or Translocations or other chromosomal abmormalities]
6. Female patients with pathological uterine cavity
7. Number of retrieved MII oocytes < 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 (lupus, chronic liver or kidney disease, body mass index (BMI) >35, uncontrolled hypertension, anti-phospholipid antibody, thrombophilia, insulin dependent diabetes)

Date of first enrolment
01/12/2011

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Italy

Study participating centre
Via di Castel Giubileo, 11
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Sponsor information

Organisation
BlueGnome Ltd (UK)

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Sponsor type
Industry

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ROR
https://ror.org/027c2yv63

Funder(s)

Funder type
Industry

Funder Name
Genoma Molecular Genetics Laboratory (Italy)

Funder Name
Genera (Italy)

Funder Name
BlueGnome (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