

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	<input type="checkbox"/> Prospectively registered
Registration date 09/12/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 12/06/2017	Condition category Urological and Genital Diseases	<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

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

Protocol serial number
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 screening (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

Primary study design

Interventional

Study design

Prospective randomised double-blinded study

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Azoospermic male partner
2. Severe male factor infertility defined as ejaculate sperm of < 1 million 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 abnormalities]
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
Rome
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00138

Sponsor information

Organisation
BlueGnome Ltd (UK)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration