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Embryo development of fresh versus vitrified metaphase II after intracytoplasmic sperm injection (ICSI): a sibling-oocyte study

Submission date
18/05/2009

Registration date
29/05/2009

Last Edited
21/12/2009

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
CVG02092008

Study information

Scientific Title
Embryo development of fresh versus vitrified metaphase II after intracytoplasmic sperm injection (ICSI): a prospective randomised active-controlled parallel group sibling-oocyte study

Study objectives
Non-inferiority trial in order to evaluate the effectiveness of the oocyte vitrification procedure, effectiveness being defined by fertilisation rate after intracytoplasmic sperm injection (ICSI) per warmed oocyte.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local medical ethics committee (Clinica Valle Giulia, Roma) approved on the 1st September 2008

Study design
Randomised active controlled parallel group trial

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Intracytoplasmic sperm injection cases, oocyte vitrification

Interventions
After oocyte denudation, MII oocytes with normal morphology were randomly allocated to fresh ICSI insemination or to vitrification procedure. If pregnancy was not obtained a subsequent ICSI cycle was performed with warmed oocytes of the same cohort. In both groups, 3 oocytes were inseminated per cycle by ICSI procedure.

The vitrification and warming procedures were performed according to Kuwayama and co-Authors (2005). Commercial kits were used (Vitrification and Warming KIT, Kitazato BioPharma Co, Japan).

The vitrification procedure was performed at room temperature (RT). Oocytes were equilibrated in the equilibration solution (ES) containing 7.5% ethylene glycol (EG) and 7.5% dimethylsulfoxide (DMSO) in HEPES buffered basic culture medium M-199 with 20% synthetic serum substitute (SSS). To perform the equilibration gradually, the oocytes were first placed in a 20 microlitre drop of M199+20%SSS and, immediately, after mixed with a second 20 microlitre drop of ES. After 3 minutes incubation, a third 20 microlitre drop of ES solution was mixed. Finally, the oocyte were moved in a pure drop of 20 microlitre ES and incubated for an additional 6 - 9 minutes. The oocytes (1 to 3, contemporaneously) were then transferred in 1 ml of vitrification solution (VS) containing 15% EG, 15% DMSO and 0.5M sucrose in M199+20%SSS for 1 minute. The oocytes were then placed on the Cryotop strip in a single small drop of VS. Much care was driven to re-aspirate, as much as possible, the excess of VS in such way to leave just a thin layer around each oocyte. The Cryotop was then immediately submerged into liquid nitrogen. Finally, the plastic cap was pulled over the Cryotop inside the liquid nitrogen and the sample was stored submerged in liquid nitrogen.

The first step of warming procedure was performed at 37°C. The cap was removed in liquid nitrogen and the cryotop was immediately submerged in 1 ml of warming solution containing 1.0 M sucrose in M199+20%SSS. After 1 minute, oocytes were placed in 1 ml solution containing 0.5 M sucrose, and incubated at RT for 3 minutes. Finally, the oocytes were washed at RT for 6 minutes in 2 different dishes containing 1 ml basic medium M199+20%SSS each, and transferred into 1 ml culture media. Degenerated oocytes were removed from the cohort.

The surviving oocytes were co-cultured at 37°C (6% CO2 and 5%O2) for exactly 2 hours before ICSI.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Non-inferiority in fertilisation rates calculated per warmed and per injected oocyte, assessed 16 - 18 hours post-treatment (ICSI).

Secondary outcome measures
1. Pronuclear morphology
2. Embryo development, assessed 42 - 44 hours post-treatment
3. Patient's baseline characteristics
4. Clinical outcomes

Overall study start date
02/09/2008

Completion date
10/03/2009

Eligibility

Key inclusion criteria

Between September 2008 and February 2009 consecutive patients not older than 42 years of age, presenting greater than 6 normal appearing metaphase II (MII) oocytes and undergoing ICSI treatment with ejaculated sperm in the Centre for Reproductive Medicine GENERA in Rome.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
40

Key exclusion criteria
1. Female partner older than 42 years old
2. Less than 6 normal appearing MII oocytes retrieved
3. Surgically extracted spermatozoa
4. Very severe oligoastenoteratozoospermia (motile sperm count less than 500,000/ml after preparation)
5. Patients enrolled in our polar body biopsy programme

Date of first enrolment
02/09/2008

Date of final enrolment
10/03/2009

Locations

Countries of recruitment
Italy

Study participating centre
G.EN.E.R.A.
Rome
Italy
00197

Sponsor information

Organisation

G.EN.E.R.A. - Clinica Valle Giulia (Italy)

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Sponsor type
Hospital/treatment centre

Website
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ROR
https://ror.org/05aq4y378

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
G.EN.E.R.A. - Clinica Valle Giulia (Italy)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2010		Yes	No