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Trial comparing blastocyst transfer with cleavage stage transfer in women with increased maternal age

Submission date
27/10/2011

Recruitment status
No longer recruiting

Registration date
28/12/2011

Overall study status
Completed

Last Edited
14/11/2017

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) techniques help people with fertility problems to have a baby. ICSI (intracytoplasmic sperm injection) is an IVF technique in which a single sperm is injected into the centre of an egg. The resulting embryo can be transferred into the woman's womb when they are at cleavage stage (day 2 to 3) or at blastocyst stage (day 5 to 6). The aim of this study is to compare blastocyst stage transfer and cleavage stage transfer in women undergoing IVF/ICSI.

Who can participate?
Women aged 37 to 42 undergoing IVF/ICSI

What does the study involve?
Participants are randomly allocated to undergo either blastocyst stage transfer or cleavage stage transfer. Live birth rate, delivery rate, multiple pregnancy rate, health of the child, and time to pregnancy are compared in the two groups.

What are the possible benefits and risks of participating?
These strategies are expected to result in comparable delivery rates, but the time required to achieve pregnancy is expected to be shorter in the blastocyst transfer group.

Where is the study run from?
GENERA Centre for Reproductive Medicine (Italy)

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

Who is funding the study?
GENERA Centre for Reproductive Medicine (Italy)

Who is the main contact?
Dr Laura Rienzi
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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
032012

Study information

Scientific Title
Blastocyst stage vs cleavage stage transfer in women with increased maternal age: a prospective randomised controlled trial

Study objectives
A prospective randomised controlled trial to compare two strategies: blastocyst stage transfer and cleavage stage transfer in Intracytoplasmic Sperm Injection (ICSI) cycles of women aged between 37 and 42 years old. These strategies are expected to have comparable cumulative outcomes for delivery rates. Blastocyst transfer is expected to have favorable outcomes per transfer. The hypothesis is the non-inferiority of cleavage stage strategy when the delivery rate is calculated cumulatively. However, the time to achieve the pregnancy is expected to be shorter in the blastocyst transfer group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Medical Ethics Committee [Clinica Valle Giulia Ethics Committee], 20/09/2011

Study design
Prospective randomized 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 in females aged between 36 and 42 years

Interventions
Patients will be randomised on the day of ovum pick up by a independent operator to:
1. Blastocyst transfer:
1.1. Ovarian stimulation by agonist or antagonist protocol
1.2. Ovum pick up performed 36 hours after human chorionic gonadotropin (HCG) administration
1.3. In vitro fertilization performed by intracytoplasmic sperm injection (ICSI)
1.4. In vitro culture performed with sequential media in 6% CO2 and 5% O2 atmosphere
1.5. Embryo transfer on day 5 two best quality blastocyst. Remaining blastocyst preserved by vitrification procedure
1.6. Luteal support by Progesterone 200 mg vaginally three times a day from oocyte retrieval plus one day

2. Cleavage stage transfer:
2.1. Ovarian stimulation by agonist or antagonist protocol
2.2. Ovum pick up performed 36 hours after Human chorionic gonadotropin (HCG) administration
2.3. In vitro fertilization performed by intra-cytoplasmic sperm injection (ICSI)
2.4. In vitro culture performed with sequential media in 6% CO2 and 5% O2 atmosphere
2.5. Embryo transfer on day 3 two best quality embryos. Remaining embryos preserved by vitrification procedure
2.6. Luteal support by Progesterone 200mg vaginally three times a day from oocyte retrieval plus one day

Intervention Type
Procedure/Surgery

Primary outcome measure

Cumulative live birth rate after blastocyt or cleavage stage strategy including pregnancies from fresh + cryoembryos transferred within 6 months after the end of the treatment

Secondary outcome measures
1. Delivery rate per transfer
2. Multiple pregnancy rate
3. Pregnancy/childbirth: all women will be contacted to ask information on the delivery and on the health of the child: week of delivery, weight of the child, major and minor malformation
4. Time to pregnancy: the time to obtain the pregnancy from ovum pick up

Overall study start date
01/11/2011

Completion date
01/12/2012

Eligibility

Key inclusion criteria
1. Female patients aged between 37 and 42 years undergoing an IVF/ICSI attempt at the GENERA centre for Reproductive Medicine in Rome
2. History of less than 3 failed IVF/ICSI cycles
3. ≥6 MII retrieved
4. Signed consent form

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
400

Key exclusion criteria
1. Woman younger than 37 years and older than 42 years
2. Positive serology for Hepatitis B, C or HIV
3. Diminished ovarian reserve: early follicular serum FSH > 10 IU/l and/or poor response during earlier COH/IVF or COH/ICSI (less than 6 follicles)
4. Persisting ovarian cysts > 30 mm diameter
5. Severe male factor infertility (Azoospermia)

Date of first enrolment
01/11/2011

Date of final enrolment
01/12/2012

Locations

Countries of recruitment
Italy

Study participating centre
GENERA Centre for Reproductive Medicine
Rome
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Sponsor information

Organisation
GENERA Centre for Reproductive Medicine (Italy)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05aq4y378

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
GENERA Centre for Reproductive Medicine (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