

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

Submission date 27/10/2011	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 28/12/2011	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 14/11/2017	Condition category Urological and Genital Diseases	☐ 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

rienzi@generaroma.it

Contact information

Type(s)

Scientific

Contact name

Dr Laura Francesca Rienzi

Contact details

Via De Notaris 2B

Rome

Italy

00197

+39 (0)33 56 153 691

rienzi@generaroma.it

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

Italy

00197

Sponsor information

Organisation

GENERA Centre for Reproductive Medicine (Italy)

ROR

<https://ror.org/05aq4y378>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

GENERA Centre for Reproductive Medicine (Italy)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration