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Comparison of human fresh vs aseptically vitrified oocytes

Submission date
30/10/2015

Recruitment status
No longer recruiting

Registration date
04/11/2015

Overall study status
Completed

Last Edited
03/11/2015

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
About one in six couples suffer from fertility problems (inability to get pregnant). Infertility can be caused by many different factors in the man, the woman or both. Infertility in women is most often related to ovulation (the monthly release of an egg). Healthy women release an egg part-way through their menstrual cycle, which then has the potential to become fertilised by sperm and develop into a baby. In some cases, women are unable to produce eggs at all or can only produce very low quality eggs. A common treatment for this is egg donation. Healthy women under the age of 35 (donors) are able to donate egg cells (oocytes). These oocytes are then implanted in the infertile woman's (recipient) womb after they have been fertilised with their partner's sperm. Many women now choose to donate their eggs so that they can be frozen (cryopreservation) in order to be use them at a later date. The egg is the largest cell from the human body and contains a lot of water. In some cases, the freezing process forms ice crystals which destroy the egg. One way to avoid this is to "flash-freeze" the eggs using liquid nitrogen (vitrification). This process can be open (which allows direct contact between the medium (environment) containing the oocytes and the liquid nitrogen), or closed (where this contact is prevented). Currently, most studies which look at the effectiveness of vitrified eggs use the open vitrification system, and so more research is needed to find out whether closed vitrification is just as effective. The aim of this study is to find out whether using eggs frozen using closed vitrification is as safe and effective as using fresh eggs.

Who can participate?
Donors are healthy women with normal ovaries aged up to 32 years, and recipients are women aged up to 50 years who have not previously received donated eggs.

What does the study involve?
Each donation cycle (28 days), involves two recipients per donor. Each donor provides two eggs, one of which is frozen using the closed vitrification process. The recipient women are randomly allocated to one of two groups. For women in the first group, a fresh oocyte is fertilised with their partner's sperm before the resulting embryo is placed (implanted) in the womb. For women in the second group an oocyte which has been frozen using the closed vitrification technique is fertilised with their partner's sperm before being implanted in the womb. The women in both groups are monitored so that the success rate of the implantation (pregnancy) can be recorded.

What are the possible benefits and risks of participating?
Participants may benefit from pregnancy as a result of taking part in the study. Risks of participating include the possibility that the oocytes will be lost or will not become fertilized in each cycle.

Where is the study run from?
Iakentro Advanced Medical Center (Greece)

When is the study starting and how long is it expected to run for?
January 2014 to December 2014

Who is funding the study?
Iakentro Advanced Medical Center (Greece)

Who is the main contact?
Mr Achilleas Papatheodorou

Contact information

Type(s)
Scientific

Contact name
Mr Achilleas Papatheodorou

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Additional identifiers

Protocol serial number
IRB 1/14 & 808a/8-3-2011

Study information

Scientific Title
Fresh vs aseptically vitrified oocytes: A prospective observational cohort study

Acronym
VICSI OD

Study objectives
Is it possible to vitrify oocytes in an aseptic way and to maintain comparable clinical results to fresh oocytes?

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Institutional Review Board of the Ioannina Medical School, 08/03/2011, ref: 808a/8-3-2011
2. Iakentro Review Board, 19/01/2014, ref:1/2014

Study design
Prospective observational cohort study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Oocyte donation

Interventions
The cryopreservation technique used is vitrification and more specifically the closed vitrification system, in order to achieve aseptically conditions. The human oocytes are exposed in solutions with cryoprotectans before they are loaded in carriers which are inserted in a protective straw which will be thermo-sealed and then plunged in liquid nitrogen. After a short period of time (1-3 months, depending the case) the oocytes are warmed and used in the patients. Intracytoplasmic sperm injection is performed to these oocytes in order to be fertilized. The resulting embryos are cultured until day 5 of their development. Some embryos are transferred to the recipients and the remaining are cryopreserved. Clinical results are monitored in each case, until the birth of the children (9 months after the embryo transfer).

Intervention Type
Other

Primary outcome(s)
1. Pregnancy rate per cycle, confirmed by the rise of serum b-HCG concentrations, 14 days after embryo transfer
2. Clinical pregnancy rate per cycle, defined by the appearance of a gestational sac and a fetal heartbeat at 8–10 weeks of gestation
3. Ongoing pregnancy rate per cycle, considered the number of pregnancies with fetuses displaying heart activity beyond 12 weeks of gestation per cycle

Key secondary outcome(s))
1. Oocyte survival rate, defined as the number of oocytes that survived out of the total number of oocytes warmed, is evaluated 2 hours after the warming of the oocytes
2. Fertilization rate, defined as the number of fertilized oocytes out of the number of oocytes survived, evaluated 16-20 hours after the injection of a spermatozoon to the oocytes
3. Cleavage and top cleavage rate, was defined as the number of cleavage embryos, top quality

cleavage embryos respectively out of the total number of fertilized oocytes, evaluated 3 days after the injection of a spermatozoon to the oocytes
4. Blastocyst and the top blastocyst rate, defined as the number of blastocysts and top quality blastocysts respectively out of the total number of fertilized oocytes, evaluated 5 days after the injection of a spermatozoon to the oocytes

Completion date
31/12/2014

Eligibility

Key inclusion criteria
Oocyte donor inclusion criteria:
1. Up to 32 years old
2. Body mass index of less than 30 kg/m2
3. Regular menstrual cycles of 25–35 days
4. Two normal ovaries based on transvaginal scan findings
5. No polycystic ovary syndrome
6. No known endometriosis
7. No gynecological or medical disorders
8. Agreed to donate their oocytes for treatment anonymously and altruistically
9. Known fertility and good ovarian response
10. Blood sample was collected for karyotype and screening for previous viral infection (hepatitis B and C, human immunodeficiency virus, syphilis) thalassemia and cystic fibrosis
11. A single stimulation cycle was included for each donor

Recipient inclusion criteria:
1. Up to 50 years old
2. No history of endometriosis
3. First oocyte donation cycle
4. The recipients and their partners underwent blood screening similar to the donors, hysterosalpingogram and a diagnostic hysteroscopy had eliminated cases presenting hydrosalpinx or intrauterine pathology
5. The recipients had a mock transfer in a cycle previous to their donation cycle and if difficulty was encountered a cervical dilatation was performed
6. The recipient’s partner had no severe male infertility indication

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria

Donor exclusion citeria:
Less than 15 retrieved mature oocytes

Recipient exclusion criteria:
1. More than 2 previous failed oocyte donation cycles
2. Severe male factor infertility in partner

Date of first enrolment
19/01/2014

Date of final enrolment
15/12/2014

Locations

Countries of recruitment
Greece

Study participating centre
Iakentro Advanced Medical Center
Agiou Vasiliou 4
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Sponsor information

Organisation
Iakentro Advanced Medical Center

ROR
https://ror.org/05mnrce88

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Iakentro Advanced Medical Center

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available