ISRCTN13118173 https://doi.org/10.1186/ISRCTN13118173

Assessing quality of human embryos cultured in a closed system compared to embryos cultured in a conventional incubator

Submission date
20/05/2013

Recruitment status
No longer recruiting

Registration date
17/07/2013

Overall study status
Completed

Last Edited
17/12/2014

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
During in vitro fertilisation (IVF), a technique which helps couples to have a baby, one of the most important and discussed issues is how to select the right embryo for transfer to the womb. Today, this selection is made by removing the embryos from the incubator in which they are cultured, to be looked at for a short time under a microscope. This can only be done a few times during the growth of the embryo, since human embryos are very sensitive to changes in the environment that occur when they are taken out from the incubator. The aim of this study is both to introduce better ways to grow embryos during the first days, and also to improve the selection of the best embryo for transfer. We know that the time taken for each cell division is the key factor that determines the overall quality of the embryo. We also know that having the correct number of cells (not too few, not too many) at a certain time during development is of great importance for the embryo to grow in the womb and for the birth of a child. However, these things are difficult to follow and we have not been able to study the development of the embryo continuously until a few years ago.

Who can participate?
In this study we are asking patients with fertility problems and who are going through their first cycle of IVF treatment to participate. They can only participate in the study once.

What does the study involve?
Patients are randomly allocated to one of two groups. We will either let the embryos grow in a special kind of incubator with a camera inside and a screen on the outside (treatment group) or in a standard incubator (control group). By growing in the special incubator, the embryos can be photographed at specific times over several days. This results in a continuous film of their development called time-lapse imaging. This will allow us to follow the growth of the embryos without removing them from the incubator, which is believed to increase the wellbeing of the embryos. In addition, we will be able to see exactly when they go through each cell division.

What are the benefits and risks of participating in this study?
The possible benefits are that embryos will be growing in a better environment, and that we

may be able to better select the right embryo for the transfer. There are no risks in participating, the only difference in their treatment is that their embryos will be growing in a different incubator to the standard one.

Where is the study run from?
This study is run at Sahlgrenska University Hospital, Gothenburg, Sweden.

When is the study starting and how long is it expected to run for?
The recruitment of patients started in May 2010 and will run until December 2013.

Who is funding the study?
This study is funded by Ferring Pharmaceuticals, UK.

Who is the main contact?
Prof Kersti Lundin
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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
N/A

Study information

Scientific Title

A randomised control trial assessing quality of human embryos cultured in a closed, optimised system with time-lapse compared to embryos cultured in a conventional incubator

Study objectives
Our hypothesis is that culture in a closed system with minimal fluctuations in temperature and pH will result in more embryos of high quality and that the variables (cleavage time and synchronicity), will correlate with the morphological embryo quality and survival after freezing and thereby constitute novel independent predictors for implantation. These variables could then be used to study the effects of different culture conditions with the purpose to culture and select embryos with the highest potential for implantation and birth of a (single) child.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethical Review Board,Gothenburg, Sweden; 09/12/2009; Dnr: 666-09

Study design
Single-centered, prospective, randomised controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Screening

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
Human embryo culture and fertility

Interventions
All of the patients' embryos are randomised to be cultured in an embryoscope with time-lapse or to be conventionally cultured in an incubator without time-lapse.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

The primary end variable is the number of cleaved embryos of high quality

Secondary outcome measures
Secondary end variables are fertilisation, implantation rate and birth rate

Overall study start date
01/05/2010

Completion date
01/12/2013

Eligibility

Key inclusion criteria
Patients who undergoes their first in vitro fertilisation (IVF)/intra-cytoplasmic sperm injection (ICSI) cycle and obtains at least one oocyte

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
357

Key exclusion criteria
1. Patients who have already participated in the study
2. Patients going through egg donation treatment

Date of first enrolment
01/05/2010

Date of final enrolment
01/12/2013

Locations

Countries of recruitment
Sweden

Study participating centre

Reproductive Medicine
Gothenburg
Sweden
413 45

Sponsor information

Organisation
Unisense FertiliTech (Denmark)

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Sponsor type
Industry

ROR
https://ror.org/02wr25f53

Funder(s)

Funder type
Industry

Funder Name
Ferring Pharmaceuticals (UK)

Funder Name
Gothenburg University (Sweden)

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	01/02/2015		Yes	No