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Clinical efficiency of a ready-to-use medium for human embryo culture supplemented with growth factors in patients with previous in vitro fertilization failures

Submission date
12/01/2016

Recruitment status
No longer recruiting

Registration date
26/01/2016

Overall study status
Completed

Last Edited
26/01/2016

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
In order for a woman to become pregnant, the fertilized egg must attach (implant) itself to the lining of the womb. In vitro fertilization (IVF) is a technique used to help people with fertility problems to have a baby. During IVF, couples donate their own sperm and eggs (or use sperm and eggs from a donor). The egg is fertilized by the sperm outside of the body to create an embryo and then returned to the woman's womb to develop. Although IVF has become more and more successful in recent years, there is still a relatively high failure rate. Recent studies have shown that a natural chemical released by white blood cells called Granulocyte macrophage colony-stimulating factor (GM-CSF) could be directly related to the success of IVF. In normal pregnancies, levels of this chemical have been found to be higher, suggesting that it plays a role in implantation and embryo development. Embryogen (Origio) is a ready-to-use growth medium (environment) which contains GM-CSF. Some previous studies have shown that using this medium in the fertilization of eggs in IVF treatment could help to improve the chance of pregnancy in women who have previously had a miscarriage. The aim of this study is to find out whether using Embryogen in the IVF treatment of women who have had previous unsuccessful IVF treatment could help to improve the chance of pregnancy.

Who can participate?
Women aged between 25 and 45, who have had at least one previous IVF treatment that did not result in pregnancy.

What does the study involve?
Participants are all treated using hormonal injections between day 12 and 20 of their menstrual cycle to stimulate their ovaries to release eggs (oocytes). They are then given further hormone treatment and the eggs are retrieved using a needle (to such them out of the ovary). The participants are then randomly allocated to one of two groups. For those in the first group, the best quality eggs are selected and are fertilized using Embryogen as the growth medium. For those in the second group, the best quality eggs are selected and are fertilized using ISM1 as the

growth medium (usual growth medium used). Fertilization for all eggs is done using Intracytoplasmic sperm injection (ICSI), in which a single sperm is injected directly into each egg. Two to three days later, the embryos are then implanted into the respective participants' wombs. After thirty days, the amount of embryos that successfully attached to the womb lining (implantation rate) and the amount of women who became pregnant are measured for participants in both groups.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with taking part in this study.

Where is the study run from?
Gynepro Medical S.R.L. (Italy)

When is the study starting and how long is it expected to run for?
January 2012 to December 2016

Who is funding the study?
Gynepro S.R.L. (Italy)

Who is the main contact?
Dr Lodovico Parmegiani

Contact information

Type(s)
Scientific

Contact name
Dr Lodovico Parmegiani

Contact details
GynePro Medical Centers
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40137

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
GP-1-2015

Study information

Scientific Title
Clinical efficiency of a ready-to-use medium for human embryo culture supplemented with granulocyte macrophage-colony stimulation factor GM-CSF (Embryogen ™) in patients with previous unsuccessful In vitro fertilization IVF-ICSI attempts, a prospective randomised study

Study objectives
The aim of this study is to evaluate if the addition of granulocyte macrophage-colony stimulation factor GM-CSF increases the clinical efficiency of human embryo culture media in patients with previous unsuccessful attempts of in vitro fertilization.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Medical Ethics Committee of GynePro Medical Center, 14/12/2011, ref: GP14. 11.2011

Study design
Prospective randomized controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

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 (ICSI) and embryo culture

Interventions
Participants are randomly allocated to one of two groups.

Group 1: Participants receive intracytoplasmic sperm injection (ICSI) treatments carried out using ISM1 for embryo culture and transfer.

Group 2: Participants receive intracytoplasmic sperm injection (ICSI) treatments carried out using Embryogen for embryo culture and transfer.

For both groups, participants undergo controlled ovarian stimulation between day 12 and 20 of their menstrual cycle using gonadotropin-releasing hormone analogs in combination with a graded gonadotropin administration. Oocyte retrieval is performed 35 hours after ovulation

induction with either 5,000 or 10,000 IU of human chorionic gonadotropin (hCG). High quality oocytes (colourless and of regular shape, with regular zona pellucida and small perivitelline space without debris, homogeneous cytoplasm and no vacuoles or granulations) are cultured at 37°C in an atmosphere of 6% CO2, in either the ISM1 or Embryogen medium. Insemination by ICSI of the best available MII oocytes, in accordance with the Italian law regulating Assisted Reproductive Technology, is then used between 2 and 3 days after donation.

The follow up will be completed at confirmation of clinical pregnancy by ultrasound check of gestational chamber, 30 days after the embryo transfer.

Intervention Type
Other

Primary outcome measure
Implantation rate (defined as the number of implanted embryos per number of transferred embryos) is measured 30 days after embryo transfer.

Secondary outcome measures
Pregnancy rate (defined as the number of pregnancies per number of transferred embryos) is measured using ultrasound of gestational chamber 30 days after embryo transfer.

Overall study start date
01/01/2012

Completion date
01/04/2016

Eligibility

Key inclusion criteria
1. Female patients with at least one previous unsuccessful IVF attempt, in which a clinical pregnancy was not established (including biochemical pregnancies or miscarriages)
2. Aged between 25 and 45

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
500

Key exclusion criteria

1. Women older than 45 years old
2. Patients with male partners with testicular spermatozoa or severe oligoastenoteratozoospermia (total sperm number less than 1,000,000 and sperm motility less than 5%)

Date of first enrolment
01/01/2012

Date of final enrolment
01/07/2012

Locations

Countries of recruitment
Italy

Study participating centre
Gynepro Medical S.R.L.
Via Tranquillo Cremona, 8
Bologna
Italy
40137

Sponsor information

Organisation
Gynepro S.R.L.

Sponsor details
via T. Cremona, 5
Bologna
Italy
40137

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03segdh23

Funder(s)

Funder type
Industry

Funder Name
Gynepro S.R.L.

Results and Publications

Publication and dissemination plan
Planned submission of an abstract including preliminary data to an international IVF meeting.

Intention to publish date
30/09/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request