ISRCTN13123887 https://doi.org/10.1186/ISRCTN13123887

Is it useful to continue administration of gonadotropin releasing hormone (GnRH) agonist after embryo transfer?

Submission date
02/02/2014

Registration date
20/02/2014

Last Edited
20/02/2014

Recruitment status
No longer recruiting

Overall study status
Completed

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
Many clinical studies have tried to improve implantation and pregnancy rates after in vitro fertilisation (IVF) / intracytoplasmic sperm injection (ICSI) Many researchers think that the relatively low pregnancy rate in IVF and ICSI is due to a problem with the endometrium (lining of the uterus) in the luteal phase (the part of the menstrual cycle which begins immediately after ovulation). Estrogen was tried in addition to the standard progesterone treatment. However, no improvement was found by adding estrogen.
Several researchers tried to improve the implantation rate by giving gonadotropin releasing hormone agonist (GnRHa) injection in the luteal phase in different doses. The results of these studies are controversial. The aim of this study is to find out if there is evidence that administration of GnRHa during the period following embryo transfer will improve implantation and pregnancy rates.

Who can participate?
Any woman below the age of 40 years who was assigned to start IVF/ICSI treatment.

What does the study involve?
Participants were randomly allocated to one of two study groups.
The first group will receive GnRHa after the embryo transfer and the other group will not receive GnRHa.

What are the possible benefits and risks of participating?
There is a possible improvement of implantation and pregnancy rate. According to the previously published studies on this subject there are no risks to the patients and no possible reduction in the pregnancy rate.

Where is the study run from?
The Egyptian IVF Center (Egypt).

When is the study starting and how long is it expected to run for?
The study started in July 2012 and is expected to run until February 2014.

Who is funding the study?
Egyptian IVF Center (Egypt).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
A prospective randomized study evaluating the effect of administrating GnRH agonist (GnRHa) in the luteal phase on the outcome of ICSI cycles stimulated with long GnRHa protocols

Study objectives
There are controversial data in the literature concerning the effect of continuation of GnRHa in the luteal phase on the pregnancy rate. This is a randomized study to evaluate the value of GnRHa administration in the luteal phase and to perform a meta-analysis with previous similar randomized studies to further strengthen the outcome of the results.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Committee of Ethics and Research of the Egyptian IVF Center, 01/06/2012

Primary study design
Interventional

Study design

Single-center prospective randomized study

Study type(s)
Other

Health condition(s) or problem(s) studied
Infertility treated by ICSI

Interventions
The number of patients included in both groups was chosen based upon a special statistical calculation which makes the outcome of the study meaningful. After the pre-calculated number is reached the study is declared finished and we will send data to a statistician to find out of administration of GnRHa in the luteal phase is useful and effective and accordingly we may advise patients to take or not take this medicine after embryo transfer routinely.

Participants are randomised to two arms:
1. GnRHa is injected in luteal phase plus the usual luteal phase support
2. The usual luteal phase support only

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Clinical pregnancy rate, which is measured by BhCG assay 2 weeks after embryo transfer followed by ultrasound at 67 weeks to detect fetal echoes and pulsation

Key secondary outcome(s)
Ongoing pregnancy rate, which is diagnosed by ultrasound examination at 2024 weeks pregnancy to document a viable pregnancy at this point

Completion date
28/02/2014

Eligibility

Key inclusion criteria
Women under 40 years old undergoing intracytoplasmic sperm injection (ICSI) in the first or second trial and using the long GnRHa protocol

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Donor eggs
2. Patients aged 40 or older
3. Pre-implantation Genetic Diagnosis (PGD) cycles
4. Patients with fibroids or congenital anomalies of the uterus

Date of first enrolment
01/07/2012

Date of final enrolment
28/02/2014

Locations

Countries of recruitment
Egypt

Study participating centre
10 Geziret El Arab St.,
Cairo
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12411

Sponsor information

Organisation
The Egyptian IVF Center (Egypt)

ROR
https://ror.org/035aahr55

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The Egyptian IVF Center (Egypt)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration