

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

Submission date 02/02/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 20/02/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 20/02/2014	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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?
Prof. Mohamed Aboulghar
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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 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

Study design

Single-center prospective randomized 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

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 measure

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

Secondary outcome measures

Ongoing pregnancy rate, which is diagnosed by ultrasound examination at 2024 weeks pregnancy to document a viable pregnancy at this point

Overall study start date

01/07/2012

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

Age group

Adult

Sex

Female

Target number of participants

446

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

Egypt

12411

Sponsor information

Organisation

The Egyptian IVF Center (Egypt)

Sponsor details

3 St 161 Hadaek El Maadi

Cairo

Egypt

11431

+20 (0)2 2525 4944

ivf@link.net

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/035aahr55>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

The Egyptian IVF Center (Egypt)

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