

The use of a flexible (GnRH) antagonist versus minidose long GnRH agonist for ovarian stimulation in poor-responder patients undergoing the (IVF) program

Submission date 16/06/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 29/07/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 17/10/2017	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Controlled ovarian hyperstimulation is a technique used in assisted reproduction (e.g. IVF) where fertility drugs are used to induce the release of eggs from the ovaries. Poor ovarian response to controlled ovarian stimulation is a major concern in assisted reproduction. The use of GnRH agonist and antagonist drugs has proved to be effective at improving pregnancy rates in poor responders. However, various studies have reported conflicting results regarding which is superior in this category of patients, and more research is needed in this area. Therefore the aim of this study is to compare the effectiveness of a flexible GnRH antagonist treatment versus a low dose (minidose) long GnRH agonist treatment in poor-responder patients undergoing IVF.

Who can participate?

Women undergoing IVF who are poor responders to ovarian stimulation (e.g. developed less than four eggs in previous IVF cycles)

What does the study involve?

Participants are randomly allocated to receive either flexible GnRH antagonist treatment or minidose long GnRH agonist treatment. The participants' eggs are retrieved and fertilised and the embryos are transferred back into their womb. The pregnancy rate per embryo transferred is compared between the two groups.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

Al-Amal Maternity Hospital (Jordan)

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

January 2009 to October 2010

Who is funding the study?
Al-Amal Maternity Hospital (Jordan)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Study information

Scientific Title
Effectiveness of a flexible GnRH antagonist versus minidose long GnRH agonist in poor-responder patients undergoing IVF: a prospective randomized trial

Study objectives
The objective of our study was to compare the efficacy of flexible gonadotropin-releasing hormone (GnRH) antagonist protocol versus minidose long GnRH agonist protocol in poor-responder patients undergoing in vitro fertilisation (IVF)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board of Al-Amal Maternity Hospital, 05/01/2009 ref: AM/ART/153

Study design
Single-center randomized controlled trial

Primary study design
Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Poor ovarian response to ovarian stimulation in IVF

Interventions

1. Random allocation was performed by an IVF physician at the start of the study using consecutive number method in 1:1 ratio
2. In this prospective randomized trial, participants were randomly assigned to receive either flexible GnRH antagonist protocol (n=62) in which Cetrorelix 0.25mg daily was added to the ovarian stimulation when the largest follicle measures ≥ 14 mm or minidose long agonist protocol (n=62) in which Triptoreline 0.05 mg daily (half the standard dose) was initiated during the luteal phase prior the treatment cycle
3. All patients in both groups received the same starting dose (450IU) of Urofollitropin for ovarian stimulation
4. This dose was adjusted after the fifth day of stimulation according to the ovarian response as evaluated by vaginal ultrasonography and measurement of estradiol and progesterone levels
5. When the leading follicle had reached a diameter of 18 mm, ovulation was triggered with 10,000 IU of HCG
6. This was followed by transvaginal ultrasound guided oocyte retrieval 35 hours later
7. In all cycles, ICSI technique was performed and embryo transfers were done 48-72 hours after oocyte retrievals
8. Luteal phase support was provided with vaginal progesterone 400 mg daily starting one day following oocyte retrieval until the day of the pregnancy test, then until 10 weeks of pregnancy if the treatment is successful
9. A serum B-HCG level was performed 15 days after oocyte collection

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Cetrorelix, progesterone, triptoreline, urofollitropin

Primary outcome(s)

The clinical pregnancy rate per embryo transfer

Key secondary outcome(s)

1. Required gonadotrophin dose
2. Days of stimulation
3. Estradiol on day of human chorionic gonadotropin (HCG)
4. Progesterone on day of HCG
5. Number of oocytes retrieved
6. Number of fertilized oocytes
7. Number of embryos obtained
8. Number of embryos transferred

Completion date

30/10/2010

Eligibility

Key inclusion criteria

Participants were poor responders to ovarian stimulation undergoing IVF program and defined as

1. Women who developed less than four oocytes in previous IVF cycles
2. Women with high basal Follicle-stimulating hormone (FSH) level ($>10\text{IU/L}$)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Patients with intrauterine pathology (endometrial polyp, intrauterine septum)
2. Patients with polycystic ovaries
3. Patients with ovarian cyst, detected on second day of cycle (baseline evaluation)

Date of first enrolment

10/01/2009

Date of final enrolment

30/10/2010

Locations

Countries of recruitment

Jordan

Study participating centre

Al-Amal Maternity Hospital

Amman

Jordan

11194

Sponsor information

Organisation

Al-Amal Maternity Hospital (Jordan)

ROR

<https://ror.org/00zszj16>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Al-Amal Maternity Hospital (Jordan)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration