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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

Registration date
29/07/2011

Overall study status
Completed

Last Edited
17/10/2017

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
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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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 ¡Ý14mm 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 measure
The clinical pregnancy rate per embryo transfer

Secondary outcome measures
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 retreived
6. Number of fertilized oocytes
7. Number of embryos obtained
8. Number of embryos transferred

Overall study start date
10/01/2009

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 (>10IU/L)

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
124

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)

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Sponsor type
Hospital/treatment centre

Website
http://www.alamalhospital.com/

ROR
https://ror.org/00zszzj16

Funder(s)

Funder type

Hospital/treatment centre

Funder Name
Al-Amal Maternity Hospital (Jordan)

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