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Clomiphene Citrate for Poor Responder women undergoing in vitro fertilisation (IVF) /intracytoplasmic sperm injection (ICSI) treatment cycles

Submission date
26/08/2010

Recruitment status
No longer recruiting

Registration date
28/03/2011

Overall study status
Completed

Last Edited
28/03/2011

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
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Mohamed Youssef

Contact details
Egyptian International Fertility and IVF Center (EIFC)
Cairo
Egypt
-
m.a.ypossef@amc.uva.nl

Additional identifiers

Study information

Scientific Title
Clomiphene Citrate for Poor Responder women undergoing in vitro fertilisation (IVF) /intracytoplasmic sperm injection (ICSI) treatment cycles: randomised controlled study

Acronym

CCPR

Study objectives
Mild stimulation in the form of combined administration of oral clomiphene citrate (CC), follicle stimulating hormone (FSH), and gonadotrophin-releasing hormone (GnRH) antagonist (fixed protocol) preceded by luteal estradiol, for poor responders elected for assisted reproduction techniques (ART) could achieve comparable outcomes in comparison with the standard long protocol.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The ethics board of the Egyptian International Fertility and IVF Center (EIFC) approved in March 2003

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Poor ovarian response

Interventions
Control group:
Thirty-five women underwent COH with a long GnRH agonist protocol: Triptorelin acetate SC (Decapeptyl® 0.1 mg, Ferring, Denmark) was administrated in the midluteal phase at a daily dose of 0.1 mg of the preceding cycle. Two weeks later, once desensitisation was achieved (E2 less than or equal to 50 pg/ml, no evidence of ovarian cysts on ultrasound and endometrial thickness less than 5 mm), ovarian stimulation with subcutaneous (s.c.) highly purified HMG Menopur® (Ferring, Denmark) 300 IU daily was commenced. Decapeptyl® was continued until the day of HCG administration.

Study group:
Thirty - five women received Luteal E2 (ethinylestradiol 2 mg [Progynova®]) two tablets daily was given till menstruation. Transvaginal ultrasound and serum progesterone were arranged on day 2 of the period. After confirmation of quiescent ovaries, 100 mg clomophene citrate was given from day 2 to 6 of the menstruation. HP HMG Menopur® (Ferring, Denmark) 3 ampoules daily from day 7, (225 IU). GnRH antagonist, cetrorelix 0.25 mg s.c. (Cetrotide® Serono Laboratories, Aubonne, Switzerland) has been given on day 6 of stimulation (fixed protocol) to prevent premature lutenisation, until the day of HCG administration.

The total duration of the intervention is 2-3 weeks. The total duration of follow up is 1-3 months.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Triptorelin acetate SC (Decapeptyl®), highly purified Human Menopausal Gonadotrophin (HMG) Menopure®, Progynova® ethinylestradiol, clomophene citrate, cetrorelix

Primary outcome(s)
1. Duration of stimulation (i.e. duration and amount of HMG used)
2. Consumption of gonadotrophins
3. Cycle cancellation rate
4. Number of mature follicles recruited
5. Total oocytes retrieved

Key secondary outcome(s)
1. Laboratory outcomes
2. Implantation rate
3. Clinical pregnancy rates, 7 weeks from positive pregnancy test

Completion date
01/01/2009

Eligibility

Key inclusion criteria
1. Women 20 - 42 years old
2. History of primary or secondary infertility (defined as the inability to conceive after 2 years of unprotected intercourse)
3. Normal menstrual cycle
4. Body mass index (BMI) less than 27 kg/m^2
5. Not taking medication for at least 1.5 months
6. Both ovaries are present
7. Basal FSH level on day 3 is less than 10 IU/L

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria

1. Clinically or medically significant systemic disease
2. Hypothalamic amenorrhoea
3. Cycle cancellation due to poor ovarian response; patients were defined as poor responders by number of dominant follicles on HCG day and number of mature oocytes less than 3

Date of first enrolment
01/04/2008

Date of final enrolment
01/01/2009

Locations

Countries of recruitment
Egypt

Study participating centre
Egyptian International Fertility and IVF Center (EIFC)
Cairo
Egypt
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Sponsor information

Organisation
Egyptian International Fertility and IVF Center (EIFC) (Eygpt)

ROR
https://ror.org/035aahr55

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (Egypt)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration