

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	<input type="checkbox"/> Prospectively registered
Registration date 28/03/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 28/03/2011	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

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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

Study design

Randomised 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 below to request a patient information sheet

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 administered 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 clomiphene 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, clomiphene citrate, cetrorelix

Primary outcome measure

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

Secondary outcome measures

1. Laboratory outcomes
2. Implantation rate
3. Clinical pregnancy rates, 7 weeks from positive pregnancy test

Overall study start date

01/04/2008

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/m²
 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

Age group

Adult

Sex

Female

Target number of participants

70

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)

Sponsor details

c/o Mohamed Abdel Fattah Mahmoud Youssef

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Egypt

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Sponsor type

Hospital/treatment centre

ROR

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

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded (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