Prospective randomised study comparing luteal phase support in in-vitro fertilisation /intracytoplasmic sperm injection patients for three weeks versus seven weeks from day of positive pregnancy test

Submission date	Recruitment status No longer recruiting	Prospectively registered		
28/12/2006		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
25/01/2007	Completed	[X] Results		
Last Edited 15/04/2008	Condition category Pregnancy and Childbirth	[] Individual participant data		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Study objectives

A question was sent to 18 in-vitro fertilisation (IVF) centres worldwide, asking about their policy of luteal phase support. A very wide variation in the duration of luteal phase support was noticed between different centres. The study will compare three weeks versus seven weeks of luteal phase support from day of positive beta-human chorionic gonadotropin (β -hCG) in IVF patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the Ethical Committee of the Egyptian IVF Center on the 15th November 2006.

Study design

A prospective randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Infertility patients treated by IVF/ICSI

Interventions

All patients receive intramuscular (IM) progesterone 50 mg daily from day of oocyte retrieval and continue for three weeks from day of positive β -hCG test, i.e. day of first ultrasound.

Patients are randomised on day of first ultrasound to:

Arm one: stop luteal phase support on day of first ultrasound

Arm two: continue luteal phase support in the form of cyclogest (micronised progesterone 400 mg) for four more weeks.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Progesterone

Primary outcome measure

Miscarriage rate in the first trimester

Secondary outcome measures

- 1. Bleeding episodes in the first trimester
- 2. Adverse reactions to progesterone

Overall study start date

20/12/2006

Completion date

20/06/2007

Eligibility

Key inclusion criteria

- 1. Patients undergoing IVF/intra-cytoplasmic sperm injection (ICSI)
- 2. Aged less than 39 years
- 3. Having at least three high quality embryos

Participant type(s)

Patient

Age group

Adult

Sex

Not Specified

Target number of participants

400 participants, 200 in each arm

Key exclusion criteria

Intra-cytoplasmic sperm injection (ICSI) using surgically retrieved sperm.

Date of first enrolment

20/12/2006

Date of final enrolment

20/06/2007

Locations

Countries of recruitment

Egypt

Study participating centre 3 St 161 Hadayek El Maadi

Cairo Egypt 11431

Sponsor information

Organisation

The Egyptian IVF-ET Center (Egypt)

Sponsor details

3 St 161 Hadayek El Maadi Cairo Egypt 11431 +20 (0)25 25 49 44 ivf@link.net

Sponsor type

Hospital/treatment centre

Website

http://www.egyptianivfcenter.com/

ROR

https://ror.org/035aahr55

Funder(s)

Funder type

Other

Funder Name

Internally funded by the Prinicipal Investigator

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/04/2008		Yes	No