ISRCTN88722916 https://doi.org/10.1186/ISRCTN88722916

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
28/12/2006

Registration date
25/01/2007

Last Edited
15/04/2008

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

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

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
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11431

Sponsor information

Organisation
The Egyptian IVF-ET Center (Egypt)

Sponsor details
3 St 161 Hadayek El Maadi
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+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