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Investigation into the effectiveness of progesterone prevention of preterm labour in women who became pregnant by in vitro fertilisation (IVF)/ intra-cytoplasmic sperm injection (ICSI)

Submission date	Recruitment status	[ ] Prospectively registered
25/06/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
25/07/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
30/07/2008	Pregnancy and Childbirth	[ ] Record updated in last year

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
Effect of progesterone administration on the duration of pregnancy after in vitro fertilisation (IVF)/ intra-cytoplasmic sperm injection (ICSI): a prospective randomised study

Study objectives
Treatment with progesterone is emerging as the standard of care for prevention of preterm delivery in women at high risk for preterm birth. Randomised controlled trials (RCTs) have generally shown efficacy in reducing the rate of recurrent preterm delivery in women with singleton pregnancies who were at high risk for preterm labour and delivery. Most of the successful trials have employed 17-alpha-hydroxyprogesterone caproate, and one trial has reported positive results using progesterone vaginal suppositories. Very few trials of progestogens have been reported for women at risk for preterm delivery because of multiple gestations.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Egyptian IVF-ET Center Ethics Committee. Date of approval: 17/06/2008 (ref: 4/2008)

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

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
Prevention of preterm labour after IVF/ICSI

Interventions
Intervention group: Natural progesterone will be administered in the form of natural Prontogest® 400 mg daily through the vaginal route (pessaries). Progesterone administration

will continue until delivery.
Control group: Standard care only

Serum progesterone will be measured at start of trial (20 weeks gestation) and at 32 weeks gestation in all participants.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Delivery <37 weeks' gestation.

Secondary outcome measures
1. Neonatal outcome
2. Incidence of prematurity
3. Admission to neonatal intensive care unit (ICU)
4. Complication of prematurity

Overall study start date
01/07/2008

Completion date
30/12/2009

Eligibility

Key inclusion criteria
Healthy women who became pregnant after IVF/ICSI (singleton or twin). Randomisation will be carried out, on average, during the 20th week of gestation.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
302

Key exclusion criteria
1. Rupture of membranes
2. Smokers
3. Major known foetal anomalies
4. Uterine anomalies

5. Cervical cerclage
6. Treatment during this pregnancy with progesterone after 12 weeks' gestation (use up to 10 weeks' gestation is permitted)
7. Contraindications to tocolysis, including foetal distress, chorioamnionitis, preeclampsia, hemodynamic instability
8. Patients treated with oral beta adrenergics for asthma
9. Age <18 years

Date of first enrolment
01/07/2008

Date of final enrolment
30/12/2009

Locations

Countries of recruitment
Egypt

Study participating centre
The Egyptian IVF-ET Center
Cairo
Egypt
11431

Sponsor information

Organisation
Marcyrl (Egypt)

Sponsor details
Habib Scientific Office
Buildings Sheraton Square No. 1227
Building No. 8C
Cairo
Egypt
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Sponsor type
Industry

Website
http://www.marcyrl.com

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
This trial is funded mainly by the Egyptian IVF-ET Center (Egypt). The cost of medication is funded by Institut Biochimique SA (IBSA; 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