

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 25/06/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 25/07/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 30/07/2008	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

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Additional identifiers

Protocol serial number
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

Study type(s)

Prevention

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(s)

Delivery <37 weeks' gestation.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration