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The effectiveness of reducing the incidence of preterm birth in IVF/ICSI twins using natural progesterone starting from the first trimester

Submission date
13/01/2014

Recruitment status
No longer recruiting

Registration date
31/01/2014

Overall study status
Completed

Last Edited
11/06/2020

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Preterm labour before the ninth month of pregnancy is a major health issue which has a high incidence among IVF patients, especially twins. Progesterone is a drug which has successfully reduced preterm birth in women who conceived naturally with a single child and who have had previous preterm deliveries. It has also showed significant prolongation of pregnancy in IVF single baby pregnancies but did not show any beneficial effect on IVF twin pregnancies. This drug was tried in twins starting on the fifth month of pregnancy. We expect that if we start the drug early on in pregnancy from the third month this might have a beneficial effect and prolong pregnancy.

Who can participate?
Pregnant women aged at least 18 years with no previous history of preterm birth or uterus abnormality.

What does the study involve?
The study will have two groups of twin IVF pregnancies. The study group will receive the study drug progesterone daily from the 12th week of pregnancy in the form of rectal suppositories and the control group will receive placebo (dummy) suppositories. The patient and the treating doctor will be blinded to the drug they are taking. Only a third party will know what drug they took.

What are the possible benefits and risks of participating?
The possible benefit is that increasing the duration of progesterone treatment starting as early as the third month could have a beneficial effect in prolonging pregnancy in twin IVF pregnancies. There are no risks to the study as natural progesterone administered through the vagina has no reported side effects and if patient is receiving the placebo it has no negative effect.

Where is the study run from?
The Egyptian IVF-ET Center, Egypt.

When is the study starting and how long is it expected to run for?
The study will start in February 2014 and is expected to last for two years.

Who is funding the study?
The Egyptian IVF-ET Center (Egypt) and IBSA (Egypt) are funding the study.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Double-blind, placebo-controlled, single-center randomized trial to study the effectiveness of reducing the incidence of preterm birth in IVF/ICSI twins using natural progesterone starting from the first trimester

Study objectives
Progesterone has proven an effective treatment for reducing the preterm birth rate and its complications in spontaneous singletons with prior history of preterm birth and those with short cervix seen at mid trimester. No effective treatment has been used for prevention of preterm birth in twin pregnancies.

The incidence of preterm birth is higher in IVF/ICSI pregnancies both singletons and twins.

A previous randomized controlled study by our group has shown a significant reduction of preterm birth rate in singleton ICSI pregnancies, however this effect could not be demonstrated in ICSI twin pregnancies.

Studies on progesterone for prevention of preterm birth who have started administration at the mid-trimester till 34 or 37 weeks no studies have been performed to check the effect of progesterone started earlier on in pregnancy from 12 weeks.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Internal Ethics Committee of The Egyptian IVF Center, 15/11/2013

Study design
Randomized controlled double blinded study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Preterm labor and twins

Interventions
Natural progesterone will be administered to the study group in the form of prontogest (IBSA Egypt) 400 mg daily through the rectal route (pessaries), starting after the first trimester scan around 12 weeks and Progesterone will continue until delivery or 37 weeks gestation. Similarly the placebo group will receive placebo pessaries to be taken daily through the rectal route starting after the first trimester scan until 37 weeks or delivery. The patient is to be blinded to the type of suppository she is receiving.

In addition all patients in study and control group will receive antimicrobial agents in the form of :
Clindamycin vaginal cream (2%) for 7 days each month starting at 12 weeks (4) and oral amoxycillin, a single dose of 3 gm once every month.

Patient is to be followed up according to the routine antenatal care protocol of our institution. Collection of data is to be done after delivery by direct contact with the patient or through the treating physician or hospital records, which should include gestational age at delivery, neonatal condition and reporting of any complications.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Delivery before 37 weeks gestation

Key secondary outcome(s))

Neonatal outcome, including:
1. NICU admission
2. Complications of prematurity
3. Neonatal death

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. Healthy pregnant females in twins after IVF/ICSI with no previous history of preterm birth
2. Age > 18 years
3. Agree to be randomized at the time of the first trimester scan (12 weeks)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
203

Key exclusion criteria
1. Smokers
2. Major known fetal anomalies
3. Uterine anomalies
4. Cervical cerclage
5. Monochorionic twins

Date of first enrolment
01/02/2014

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Egypt

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

Sponsor information

Organisation
The Egyptian IVF-ET Center (Egypt)

ROR
https://ror.org/035aahr55

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The Egyptian IVF-ET Center (Egypt)

Funder Name
IBSA (Egypt) free drug and placebo samples

Results and Publications

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 Participant information sheet	09/06/2020	11/06/2020	Yes	No

Participant information sheet	11/11/2025	11/11/2025	No	Yes