

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Duration of estrogen for luteal phase in pregnant women undergone frozen embryo transfer cycles- Randomized controlled trials Phase III

Protocol summary

Summary

We aim to evaluate the success rate of ongoing pregnancy in cases group with discontinuation of luteal phase estrogen in women undergone artificial frozen embryo transfer (FET). The study population is women who referred to Royan Institute. In this study, one hundred women were participated in each group (case and control). This study is a randomized clinical trial-phase III, double blind and blocking at the observation of gestational sac with heart beat (6 weeks of pregnancy) by ultrasound. Artificial standard long GnRH agonist protocol use for endometrial preparation. In 2-3 days of the embryo transfer cycle, the patients will receive 6mg oral estradiol that will be continued for 14 days and if endometrial thickness estimated ≥ 7 mm, intramuscularly progesterone 100 mg daily will be started for luteal phase support. Three or four days after the onset of progesterone, 2 to 3 frozen embryos will be transferred. Participants have 21-37 years old and surplus embryos from the IVF/ICSI cycles. Control group receive estrogen and progesterone from embryo transfer until 12 week of pregnancy and cases women will discontinued estrogen after observation of gestational sac with heart beat, while progesterone will remain daily use until twelfth week of pregnancy. We assessed ongoing clinical pregnancy (6 and 12 pregnancy week) and maternal levels of estrogen and progesterone at the time of the starting day of progesterone (day 15), the day of embryo transfer, 6 and 12 weeks of pregnancy.

General information

Acronym

Luteal phase support in frozen embryo transfer cycles

IRCT registration information

IRCT registration number: **IRCT201611011141N24**

Registration date: **2017-02-01, 1395/11/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-02-01, 1395/11/13

Registrant information

Name

Kiandokht Kiani

Name of organization / entity

Royan Institute

Country

Iran (Islamic Republic of)

Phone

+98 21 2230 7960

Email address

kiandokht.kiani@royaninstitute.org

Recruitment status

Recruitment complete

Funding source

Royan Institute

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2017-06-22, 1396/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Duration of estrogen for luteal phase in pregnant women undergone frozen embryo transfer cycles- Randomized controlled trials Phase III

Public title

Luteal phase support during frozen embryo transfer cycle

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with surplus embryos undergone infertility treatment cycles (e.g. OHSS, inadequate endometrium, surplus frozen embryo from any cause); Age 21-37 years; Normal BMI (18.5 < BMI < 30); IVF / ICSI or IVF or ICSI cycles with antagonists or agonists protocols; Frozen embryos on 2-3 days. Exclusion criteria: Endometrial thickness ≤ 7 mm; Egg Donors; Surrogacy; Male factor infertility with azoospermia; Age < 37 years old; Hydrosalpinx; Uterine anomalies; Myoma with a compression effect or submucosa myoma; PGD; Blastocyst embryo transfer, ZIFT and GIFT.

Age

From **21 years** old to **37 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

This study is a randomized clinical trials-phase III, double blind and blocking at the observation of gestational sac with heart beat (6 weeks of pregnancy) by ultrasound.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Royan Institute

Street address

Royan Institute, East Hafez Avenue, Bani Hashem Street, Resalat high way, Tehran, Iran

City

Tehran

Postal code

Approval date

2016-08-09, 1395/05/19

Ethics committee reference number

IR.ACECR.ROYAN.REC.1395.70

Health conditions studied

1

Description of health condition studied

Female infertility, unspecified

ICD-10 code

N97.9

ICD-10 code description

Female infertility, unspecified

Primary outcomes

1

Description

Ongoing pregnancy rate

Timepoint

6 & 12 weeks of pregnancy

Method of measurement

ultrasonography

Secondary outcomes

1

Description

Estrogen

Timepoint

start using progesterone for luteal support in FET cycle (day 15), the day of embryo transfer, 6 and 12 weeks of pregnancy

Method of measurement

Blood serum level

2

Description

Progesterone

Timepoint

start using progesterone for luteal support in FET cycle (day 15), the day of embryo transfer, 6 and 12 weeks of pregnancy

Method of measurement

Blood serum level

Intervention groups

1

Description

Discontinued of estrogen in luteal phase support in 6 week of pregnancy and fetal heart beat

Category

Treatment - Drugs

2

Description

No intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Royan Institute

Full name of responsible person

Dr Firoozeh Ghafari

Street address

Royan Institute, East Hafez Avenue, Bani Hashem Street, Resalat high way, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Royan institute, Vice chancellor for research

Full name of responsible person

Dr Firoozeh Ghafari

Street address

Royan Institute, East Hafez Avenue, Bani Hashem Street, Resalat high way, Tehran, Iran

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Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Royan institute, Vice chancellor for research

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Royan Institute

Full name of responsible person

Dr Abdolhoseyn Shahverdi

Position

PHD of Anatomy, Vice chancellor for research

Other areas of specialty/work**Street address**

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

Obstetrician and Gynecologist and Infertility, ART fellowship

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Person responsible for updating data

Contact

Name of organization / entity

Royan Institute

Full name of responsible person

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Position

M.Sc. In Genetics / Major Collaborator

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty