Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A comparison between oral Dydrogestrone with intramuscular and vaginal Progesterone for luteal phase support in IVF , frozen embryo transfer cycles.

Protocol summary

Summary

The purpose of this study was to compare intramuscular injections of progesterone with oral Dydrojestrone in transfer of frozen embryos . In this Study , We perform a randomized clinical trial on 60 patients that are candidates for frozen embryo transfer for their IVF cycles.Patients entering this study are PCOS patients excluded from previous cycles because of OHSS; Patients with thin endometer in previous fresh cycles; patient with unsuccessful previous fresh cycles; patients with ready frozen embryos. We will exclude patients if they do not develop the necessary endometrial thickness, randomly divided into three groups of 20 patients. . After preparing the endometer with estrogen, on the day that the endometrial thickness reaches 8 mm , patients will be divided randomly into three groups. (groups 1,2,3) Group one will have luteal phase support in the form of intramuscular progesterone 50 mg daily, group two will get the support by oral dydrogestrone 40 mg daily and group three will get the support with suppository vaginal progesterone 400 mg twice daily. Embryo transfer will be performed the day after starting the Progesterone. After 8 weeks, these three groups will be compared according to clinical and chemical pregnancy outcomesand abortion rates.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201406255181N15**
Registration date: **2014-08-04, 1393/05/13**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-08-04, 1393/05/13

Registrant information

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Batool Rashidi
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Vali E Asr Reproductive Health Research Center
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Recruitment status

Recruitment complete

Funding source
Vice Chancellor of Tehran University of Medical Sciences

Expected recruitment start date
2014-12-30, 1393/10/09
Expected recruitment end date
2015-12-23, 1394/10/02
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

A comparison between oral Dydrogestrone with intramuscular and vaginal Progesterone for luteal phase support in IVF , frozen embryo transfer cycles.

Public title

A comparison between oral Dydrogestrone with intramuscular and vaginal Progesterone in frozen embryo transfer in IVF cycles.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: all patients who are candidate for freeze embryo transfer

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

School of medicine, Tehran University of medical sciences

Street address

Tehran University Building,Ghods Street,Keshavarz Blvd

City

Tehran

Postal code

Approval date

2014-07-23, 1393/05/01

Ethics committee reference number

Student thesis

Health conditions studied

1

Description of health condition studied

In vitro fertilization

ICD-10 code

Z31.2

ICD-10 code description

In vitro fertilization

Primary outcomes

1

Description

Chemical pregnancy

Timepoint

two weeks after embryo teransfer

Method of measurement

BHCG blood test

2

Description

clinical pregnancy

Timepoint

Eight weeks after embryo transfer

Method of measurement

Sonography, seeing gestational sac

Secondary outcomes

1

Description

abortion

Timepoint

2- 12 weeks after starting treatment

Method of measurement

transvaginal sonography and blood test

Intervention groups

1

Description

Intervention group one: Luteal phase support with intramuscular Progestrone 50 mg from the day of 8mm endometrial thickness.

Category

Treatment - Drugs

2

Description

Intervention group two: Luteal phase support with oral Dydrogestrone daily 40 mg from the day of 8mm endometrial thickness.

Category

Treatment - Drugs

3

Description

Intervention group three: Luteal phase support with vaginal progesterone twice daily 400 mg from the day of 8mm endometrial thickness.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Valie Asr infertility Clinic
Full name of responsible person
Mahya Ghazizadeh
Street address
Keshavarz BlVd, Imam Khomeini Hospital, Vali-E-Asr Hospital.
City
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Sponsors / Funding sources

1

Sponsor
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Vice chancellor of TUMS
Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor of TUMS
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
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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