

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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 Dydrogestrone 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 endometrium 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 endometrium 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 outcomes and 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

Name

Batool Rashidi

Name of organization / entity

Vali E Asr Reproductive Health Research Center

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Iran (Islamic Republic of)

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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 transfer

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 Progesterone 50 mg from the day of 8mm endometrial thickness.

Category
Treatment - Drugs

2

Description
Intervention group two: Luteal phase support with oral Dydrogesterone 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

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor of TUMS

Full name of responsible person

Dr, Akhundzadeh

Street address

Tehran University Building, Ghods Street, Keshavarz Blvd.

City

Tehran

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**Name of organization / entity**

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Position

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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