Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of oral dydrogestrone with vaginal progesterone for luteal-phase support in IVF

Protocol summary

Summary

Objective: to compare oral dydrogestrone with vaginal progesterone for luteal-phase support in IVF. Materials and methods: We performed this prospective, randomized double-blind trial in a tertiary infertility care unit in Taleghani hospital, Tehran, Iran. inclusion criteria: Women with a history of male factor infertility, euthyroid and normoprolactinemic. undergoing controlled ovarian stimulation for IVF treatment (fresh cycle) were included in this study. exclusion criteria: Women with tubal factor, idiopathic infertility, endometriosis-related infertility and ovulatory disturbances, moreover, women with baseline FSH >12 IU and adenomyosis ,endometriosis, myoma and chronic hepatorenal disease were excluded. 80 Women with a history of male factor infertility undergoing controlled ovarian stimulation for IVF treatment (fresh cycle) randomly were divided in two groups (group A or oral dydrogesterone group and group B or vaginal cyclogest group) Group A (n =40) received 10 mg dydrogesterone QID (40mg daily) and group B (n =40) received 400 mg vaginal Progesterone (cyclogest) twice per day (800 mg daily).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013050713265N1**
Registration date: **2013-06-22, 1392/04/01**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-06-22, 1392/04/01

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

this study is supported financially by the Infertility and Reproductive Health Research Center (IRHRC),Shahid Beheshti University of Medical Sciences.

Expected recruitment start date

2012-05-01, 1391/02/12

Expected recruitment end date

2012-12-30, 1391/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of oral dydrogestrone with vaginal progesterone for luteal-phase support in IVF

Public title

Comparison of oral dydrogestrone with vaginal progesterone

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: male factor infertility; euthyroid; normoprolactinemic. . exclusion criteria: tubal factor infertility; idiopathic infertility; endometriosis-related infertility and ovulatory disturbances; baseline FSH >12

IU; adenomyosis; uterine myoma; chronic hepatorenal disease.

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Infertility and Reproductive Health Research Center (IRHRC),Shahid Beheshti University of Medical Sc

Street address
Tehran, Iran, Taleghani hospital, Parvaneh st, Yaman st,Velenjak st, Tehran, Iran.

City
Tehran

Postal code

Approval date
2013-09-23, 1392/07/01

Ethics committee reference number
92/3/8

Health conditions studied

1

Description of health condition studied
luteal-phase support in IVF cycles

ICD-10 code
N98.9

ICD-10 code description
Complication associated with artificial fertilization, unspecified

Primary outcomes

1

Description
clinical pregnancy

Timepoint
six weeks following intervention

Method of measurement
sonography and pregnancy test

2

Description
abortion

Timepoint
six weeks following intervention

Method of measurement
sonography and pregnancy test

Secondary outcomes

1

Description
luteal-phase duration

Timepoint
2 weeks following intervention

Method of measurement
patient history

Intervention groups

1

Description
group A: received 10 mg dydrogesterone QID (40mg daily) began on the day of oocyte retrieval and was continued up to 12 weeks of pregnancy.

Category
Treatment - Drugs

2

Description
group B: received 400 mg vaginal Progesterone twice per day (800 mg daily) began on the day of oocyte retrieval and was continued up to 12 weeks of pregnancy.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Infertility and Reproductive Health Research Center,Shahid Beheshti University of Medical Sciences,T

Full name of responsible person
Dr. Saghar Salehpour

Street address
: Infertility and Reproductive Health Research Center (IRHRC), IVF center,Shahid Beheshti University of Medical Sciences, Tehran, Iran, Taleghani hospital, Parvaneh st, Yaman st,Velenjak st, Tehran, Iran.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Infertility and Reproductive Health Research Center (IRHRC), IVF center,Shahid Beheshti University o
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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
Infertility and Reproductive Health Research Center (IRHRC), IVF center,Shahid Beheshti University o
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
Infertility and Reproductive Health Research Center (IRHRC), IVF center,Shahid Beheshti University o
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Person responsible for updating data

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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