

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

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

Protocol summary

Summary

Objective: to compare oral dydrogesterone 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

Maryam Tamimi

Name of organization / entity

Shahid Beheshti University of Medical Sciences

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Iran (Islamic Republic of)

Phone

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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 dydrogesterone with vaginal progesterone for luteal-phase support in IVF

Public title

Comparison of oral dydrogesterone 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 Sciences

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, Tehran

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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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Infertility and Reproductive Health Research Center (IRHRC), IVF center, Shahid Beheshti University of

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

Infertility and Reproductive Health Research Center (IRHRC), IVF center, Shahid Beheshti University of

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 of

Full name of responsible person

Dr. Saghar Salehpour

Position

Associate professor in OBGYN/IVF fellowship- chief of Taleghani hospital IVF center

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

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Position

Associate professor in OBGYN/IVF fellowship

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

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

: Infertility and Reproductive Health Research Center (IRHRC), IVF center, Shahid Beheshti University

Full name of responsible person

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Position

Gynecologist/Resident of IVF fellowship

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Web page address

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