

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Comparison of oral dydrogesterone with vaginal cyclogest for luteal support in IUI cycles

Protocol summary

Summary

Objective: Comparison of oral dydrogesterone with vaginal cyclogest for luteal support in IUI cycles. Design: A randomized multicenter clinical trial. Setting and conduct and participants including major eligibility criteria: 150 women younger than 35 years old with unexplained infertility, Proper ovulation, 2 open tubal, Not having severe or moderate problem of man and without a history of previous abdominal surgery were included in this study. Informed consent was obtained from all patients. All women received a daily 75 IU FSH and they underwent ultrasonography on 8-9 days of the menstrual. In patients who had 3-4 follicles with a diameter of more than 18 mm, HCG to release oocytes was injected and IUI was performed 36 hours later. 2 days after IUI, Patients randomly were divided in two groups: Group A or oral dydrogesterone group (n=75) and group B or vaginal cyclogest group. Group A received 10 mg dydrogesterone twice per day and group B received 400 mg vaginal progesterone once per night. Progesterone administration was continued until 12 weeks of pregnancy. Finally, Pregnancy rates, Abortion rates, Serum levels of progesterone (on day 21 of the menstrual cycle; 7 days after IUI) and patient satisfaction in both groups were compared. Main outcome measures: Clinical pregnancy rate. Second outcomes measures: Progesterone serum level and miscarriage rates and patient acceptance.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015010220408N2**

Registration date: **2015-01-18, 1393/10/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-01-18, 1393/10/28

Registrant information

Name

Robabeh Taheripناه

Name of organization / entity

Shahid Beheshti University of Medical Sciences, Tehran, Iran.

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2558

Email address

taheripناه@sbbu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Beheshti University of Medical Science

Expected recruitment start date

2014-03-20, 1392/12/29

Expected recruitment end date

2015-01-20, 1393/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of oral dydrogesterone with vaginal cyclogest for luteal support in IUI cycles

Public title

progesterone effect on pregnancy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria; Women younger than 35 years old with unexplained infertility; Proper ovulation; 2 open tubal; Not having severe or moderate problem of man and without a history of previous abdominal surgery.
Exclusion criteria; Advanced endometriosis; Dense pelvic adhesion; Genital TB; Patients who did not refer for following up.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **148**

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 & Reproductive Health Research Center
Ethics committee of Shahid Beheshti University of

Street address

3rd floor, Taleghani Hospital, Velenjak, Shahid
Chamran highway

City

tehran

Postal code

1985711151

Approval date

2014-03-11, 1392/12/20

Ethics committee reference number

149

Health conditions studied

1

Description of health condition studied

Other complications associated with artificial fertilization

ICD-10 code

N98

ICD-10 code description

Noninflammatory disorders of female genital tract

Primary outcomes

1

Description

Clinical pregnancy rate

Timepoint

two weeks after start of intervention

Method of measurement

Transvaginal ultrasonography and pregnancy test

Secondary outcomes

1

Description

Miscariage rate

Timepoint

Until 24 weeks after start of intervention

Method of measurement

History, Physical exam, Ultrasonography

2

Description

Patients acceptance

Timepoint

Untill 12 weeks

Method of measurement

Questionare

3

Description

progestrone serum level

Timepoint

one week after start of intervention

Method of measurement

measure of blood progestrone

Intervention groups

1

Description

Intervention: Duphaston(Oral Didrogestosterone 10mg)
20mg , Twice daily until 12 weeks.

Category

Treatment - Drugs

2

Description

Intervention: Vaginal progesterone(Cyclogest 400
microgram) Daily until 12 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility & Reproductive Health Research Center
Shahid Beheshti University of Medical Science

Full name of responsible person

donya khosravi

Street address

Taleghani hospital, Velenjak, Shahid Chamran
highway, Tehran

City

tehran

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Beheshti
University of Medical Science

Full name of responsible person

zahra sadegh zadeh

Street address

3rd floor, Taleghani Hospital, Velenjak, Shahid
Chamran highway

City

tehran

Grant name

معاونت پژوهشی دانشگاه علوم پزشکی شهید بهشتی

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

Yes

Title of funding source

Vice chancellor for research, Shahid Beheshti University
of Medical Science

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 & Reproductive Health Research Centre -
Shahid Beheshti of Medical Science

Full name of responsible person

robabeh taheripanah

Position

Assistant professor of gynecology group

Person responsible for scientific inquiries

Contact

Name of organization / entity

Infertility & Reproductive Health Research Centre -
Shahid Beheshti of Medical Science

Full name of responsible person

robabeh taheripanah

Position

Assistant professor of gynecology group

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

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Person responsible for updating data

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