Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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: Progestrone 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 Taheripanah

Name of organization / entity

Shahid Beheshti University of Medical Sciences, Tehran, Iran.

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2558

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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

progestrone 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 reffer 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 Didrogesterone 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

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 شهیدبهشتی

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

Other areas of specialty/work

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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