Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Sep 2026

Comparison of the effectiveness of cyclogest and duphaston in supporting the luteal phase of infertility patients

Protocol summary

Study aim
Determining and comparing the effectiveness of cyclogest and duphaston in supporting the luteal phase of infertility patients

Design
Randomized, no-blinding clinical trial, with the parallel groups, phase 2 on 126 patients

Settings and conduct
In this randomized clinical trial study, 126 infertility patients referred to Beheshti Hospital in Isfahan will be included in the study and randomly divided into 2 groups. Patients in one group receive dydrogesterone tablets and in the other group receive progesterone suppositories. Then the clinical pregnancy rate, chemical pregnancy and Beta human chorionic gonadotropin will be compared between the two groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria include age 20-40 years old; history of infertility and candidate for IVF treatment; having a normal endometrial thickness (7 to 12 mm) and consent to participate in the study. Exclusion criteria include pelvic density adhesion; advanced endometriosis, and genital tuberculosis.

Intervention groups
Intervention group 1: patients in this group are treated with dydrogesterone tablets (Duphaston 10 mg) (Abbott Company, Netherlands) every 12 hours for 12 weeks after embryo transfer. Intervention group 2: patients in this group are treated with vaginal progesterone suppository 400 mg (cyclogest 400 mg) (Hector Company, United Kingdom) every 12 hours for 12 weeks after embryo transfer.

Main outcome variables
Clinical pregnancy rate; chemical pregnancy; Beta human chorionic gonadotropin(Beta-HCG)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200825048515N32**
Registration date: **2021-05-10, 1400/02/20**
Registration timing: **prospective**

Last update: **2021-05-10, 1400/02/20**
Update count: **0**

Registration date
2021-05-10, 1400/02/20

Registrant information

Name
Asieh Maghami Mehr

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-22, 1400/04/01

Expected recruitment end date
2021-09-22, 1400/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of cyclogest and duphaston in supporting the luteal phase of infertility patients

Public title
The effectiveness of cyclogest and duphaston in supporting the luteal phase of infertility patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 40-20 years old History of infertility and candidate for IVF treatment Normal endometrial thickness (7 to 12 mm) Consent to participate in the study
Exclusion criteria:
Having pelvic density adhesion Having advanced endometriosis Having genital tuberculosis
Age
From **20 years** old to **40 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, 126 eligible patients will be randomly selected. Then random numbers are created by computer software "Random Allocation". We randomly divide these numbers into two parts. Each number is written on paper and placed in an envelope. Then each patient is asked to choose an envelope from among the envelopes. According to the selected envelope, the patient will be assigned to one of the two groups.
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
Ethics committee of Isfahan University of Medical Sciences
Street address
Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq
City
Isfahan
Province
Isfehan
Postal code
8179964167
Approval date
2020-02-01, 1398/11/12
Ethics committee reference number
IR.MUI.MED.REC.1398.560

Health conditions studied

1

Description of health condition studied
Female infertility
ICD-10 code
N97.9
ICD-10 code description
Female infertility, unspecified

Primary outcomes

1

Description
Clinical pregnancy rate
Timepoint
Five weeks after the start of the intervention
Method of measurement
Vaginal ultrasound of the uterus

2

Description
Chemical pregnancy
Timepoint
Two weeks after embryo transfer
Method of measurement
Laboratory kit

3

Description
Beta human chorionic gonadotropin(Beta-HCG)
Timepoint
Two weeks after embryo transfer
Method of measurement
Blood test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention first group: patients in this group are treated with dydrogesterone tablets (Duphaston 10 mg) (Abbott Company, Netherlands) every 12 hours for 12 weeks after embryo transfer.
Category
Treatment - Drugs

2

Description
Intervention second group: patients in this group are treated with vaginal progesterone suppository 400 mg (cyclogest 400 mg) (Hector Company, United Kingdom) every 12 hours for 12 weeks after embryo transfer.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Isfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available