Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Jul 2026

Comparison of the effect of oral dydrogesterone with intramuscular progesterone in supporting the luteal phase in patients undergoing in vitro fertilization treatment, a non-inferiority clinical trial

Protocol summary

Study aim
Comparison of the effect of oral dydrogesterone with intramuscular progesterone in supporting the luteal phase

Design
A randomized, double parallel, single-blind, non-inferiority clinical trial , block-randomized using Sealedenvelope.com website software.

Settings and conduct
The study will be carried out in the Ibn Sina fertility clinic in Tehran. Patients undergoing infertility treatment with in vitro fertilization included in the study criteria during their luteal phase support were randomly divided into two comparison groups of dydrogesterone and intramuscular progesterone, and their clinical pregnancy outcome in the fifth week after embryo transfer will be compared with each other. In this study, the outcome assessor was blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: women between 20-40 years old, with a 5-day frozen embryo created by intracytoplasmic sperm injection (ICSI), with a normal uterine cavity.
Exclusion criteria: having serious diseases of the uterus and tubes, gender selection cycles or donation

Intervention groups
Dydrogesterone receiving group, intramuscular progesterone receiving group

Main outcome variables
Clinical pregnancy, Chemical pregnancy, Ongoing pregnancy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200421047152N5**
Registration date: **2023-11-25, 1402/09/04**
Registration timing: **registered_while_recruiting**

Last update: **2023-11-25, 1402/09/04**
Update count: **0**

Registration date
2023-11-25, 1402/09/04

Registrant information

Name
Arash Mohazzab

Name of organization / entity
Avicenna Research Institute

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-11-22, 1402/09/01

Expected recruitment end date
2024-11-21, 1403/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of oral dydrogesterone with intramuscular progesterone in supporting the luteal phase in patients undergoing in vitro fertilization

treatment, a non-inferiority clinical trial

Public title
The effect of oral dydrogesterone in supporting the luteal phase in patients undergoing in vitro fertilization treatment

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Women between 20-40 years old with a 5-day frozen embryo created by intracytoplasmic sperm injection (ICSI) Normal uterine cavity

Exclusion criteria:
Follicle stimulating hormone serum level above 12 FSH milliunits/ml History of endometriosis History of moderate to severe adenomyosis History of 3 or more previously failed embryo transfers Sex selection cycles Embryo donation cycles or surrogacy Hydrosalpinx Any type of uterine abnormalities (septum, etc.) Submucousal myoma Asherman syndrome

Age
From **20 years** old to **40 years** old

Gender
Female

Phase
3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **384**

Randomization (investigator's opinion)
Randomized

Randomization description
After obtaining informed consent, the patients were randomized and divided into two groups of 192 people pretreated with oral dydrogesterone and the other group with progesterone ampoules using permuted block randomization with size of blocks of four by Sealedenvelope.com website software. To conceal the sequence of randomization, it will be given to an independent third person, and the code will be given to the investigator one by one.

Blinding (investigator's opinion)
Single blinded

Blinding description
Since the study outcome will be assessed by someone other than the health care giver, the evaluator records the outcome information without knowing the type of intervention.

Placebo
Not used

Assignment
Parallel

Other design features
Interim analysis will be done after the entry of 200th people with the aim of primary outcome assessment and recalculation of the sample size.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethical commitee of Avicenna Reserch Institute,ACECR affiliated research institute in biotechnology

Street address
Daneshjou Blvrd. Evin. Chamran Exp.way

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Tehran

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1985743413

Approval date
2023-11-11, 1402/08/20

Ethics committee reference number
IR.ACECR.AVICENNA.REC.1402.016

Health conditions studied

1

Description of health condition studied
Infertility treated by in Vitro Fertilization

ICD-10 code
Z31.2

ICD-10 code description
In vitro fertilization

Primary outcomes

1

Description
Clinical pregnancy

Timepoint
5 weeks after embryo transfer

Method of measurement
Trans vaginal ultrasound imaging

Secondary outcomes

1

Description
Chemical pregnancy

Timepoint
Day 14 after embryo transfer

Method of measurement
Serum levels of beta human chorionic gonadotropin hormone (Beta HCG)

2

Description
Ongoing pregnancy
Timepoint
12 weeks after embryo transfer
Method of measurement
Trans abdominal ultrasound imaging

Intervention groups

1

Description
Control group: the enrolled patients enter a cycle of 45 days. In this group, the LD pill starts from the third day of menstruation and continues, and on the 21st day of the cycle, Laurelin 1.87 mg ampoule is injected.Then estradiol 2 mg every 8 hours is started on the third day of the next menstrual cycle, and ultrasound is performed 7 to 10 days later. If the thickness of the endometrium is more than 7 mm, progesterone ampoule 50 mg (Fomogex-IH) intramuscularly is prescribed every day to achieve the transformation of the endometrium. In the next stage, embryo transfer is done after 5 days (blastocyst stage embryo) will be done. In women less than 30 years old, one embryo will be transferred, and in women between 30 and 40 years old, two blast embryos will be transferred.
Category
Treatment - Drugs

2

Description
Intervention group:the enrolled patients enter a cycle of 45 days. In this group, the LD pill starts from the third day of menstruation and continues, and on the 21st day of the cycle, Laurelin 1.87 mg ampoule is injected.Then estradiol 2 mg every 8 hours is started on the third day of the next menstrual cycle, and ultrasound is performed 7 to 10 days later. If the thickness of the endometrium is more than 7 mm, then oral dydrogesterone 10 mg three times a day will be prescribed. In the next stage, embryo transfer is done after 5 days (blastocyst stage embryo) will be done. In women less than 30 years old, one embryo will be transferred, and in women between 30 and 40 years old, two blast embryos will be transferred.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Avicenna Fertility Center
Full name of responsible person
Afsaneh Mohamadzadeh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iranian academic center for education culture and research
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
Iranian academic center for education culture and research
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
Iranian academic center for education culture and research
Full name of responsible person
Somayeh Saleki
Position

Infertiltiy felowship

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available