Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Investigating the effect of daily intramuscular injection of 50 mg progesterone and 800 mg progesterone suppository on the pregnancy success rate in women with low progesterone levels

Protocol summary

Study aim

Investigating the effect of daily intramuscular injection of 50 mg progesterone and 800 mg progesterone suppository on the pregnancy success rate in women with low progesterone levels

Design

This three-phase clinical trial, with parallel groups, randomized (using the allocation randomization rule) is performed on 218 infertile women.

Settings and conduct

In this interventional study, 218 infertile women are selected by convenience sampling method in Yas Hospital. Then, 109 women will be placed in the intervention group (daily intramuscular injection of 50 mg progesterone and 800 mg progesterone suppository) and 109 women will be placed in the control group (800 mg progesterone suppository) using the random allocation method.

Participants/Inclusion and exclusion criteria

Inclusion criteria include women aged 18 to 38 years, with a three-layered endometrial pattern with sufficient thickness (7 mm) after receiving estrogen, progesterone level less than 9.2 ng/ml on the day of transfer, with at least two three-day frozen embryos of good quality (AA, AB, BB). Exclusion criteria: The presence of underlying diseases such as malignancy, advanced heart failure, cirrhosis, progressive chronic neurological diseases, and uterine disorders such as fibroids, polyps, or hydrosalpinx.

Intervention groups

In the intervention group, from the day of embryo transfer, 50 mg ampoule progesterone (intramuscular injection) is prescribed once a day in addition to 400 mg progesterone suppositories every 12 hours. While in the control group, 400 mg progesterone suppositories every 12 hours are prescribed. Then, 4 weeks after the embryo transfer, the presence of pregnancy is assessed, and in case of pregnancy, the aforementioned drugs are continued until 12 weeks after transfer, otherwise, the drugs are stopped.

Main outcome variables

Live birth is measured once at the end of the study.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150105020558N6**
Registration date: **2023-02-28, 1401/12/09**
Registration timing: **prospective**

Last update: **2023-02-28, 1401/12/09**
Update count: **0**

Registration date

2023-02-28, 1401/12/09

Registrant information

Name
Mahbod Ebrahimi
Name of organization / entity
Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 8882 7794
Email address
maebrahimi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-09, 1402/01/20

Expected recruitment end date

2023-08-22, 1402/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of daily intramuscular injection of 50 mg progesterone and 800 mg progesterone suppository on the pregnancy success rate in women with low progesterone levels

Public title

Investigating the effect of increasing the amount of prescribed progesterone on the pregnancy success rate

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women with a three-layered endometrial pattern with sufficient thickness (7 mm) after receiving estrogen Progesterone level less than 9.2 ng/ml on the day of transfer With at least two three-day frozen embryos of good quality (AA, AB, BB)

Exclusion criteria:

The presence of underlying diseases such as malignancy, advanced heart failure, cirrhosis, progressive chronic neurological diseases, and uterine disorders such as fibroids, polyps, or hydrosalpinx.

Age

From **18 years** old to **38 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **218**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation, there are 109 small envelopes containing letter A and 109 small envelopes in the same shape containing letter B in a bag, and for each patient, one envelope is selected randomly.

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

Ethical Committee of Tehran University of Medical Sciences

Street address

Ethics committee of Tehran University of Medical Sciences, School of Medicine, Pour Sina Ave., Qods Blvd.

City

Tehran

Province

Tehran

Postal code

1598718311

Approval date

2023-02-12, 1401/11/23

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.755

Health conditions studied

1

Description of health condition studied

Female infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Live birth

Timepoint

Once, after pregnancy termination

Method of measurement

The number of deliveries that resulted in a live-born neonate.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: From the day of embryo transfer, 50 mg ampoule progesterone (intramuscular injection) is prescribed once a day in addition to 400 mg progesterone suppositories every 12 hours. Then, 4 weeks after the embryo transfer, the presence of pregnancy is assessed, and in case of pregnancy, the aforementioned drugs are continued until 12 weeks after

transfer, otherwise, the drugs are stopped.

Category

Treatment - Drugs

2

Description

Control group: From the day of embryo transfer, 400 mg progesterone suppositories every 12 hours are prescribed. Then, 4 weeks after the embryo transfer, the presence of pregnancy is assessed, and in case of pregnancy, the aforementioned drug is continued until 12 weeks after transfer, otherwise, the drugs are stopped.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yas Hospital

Full name of responsible person

Mahbod Ebrahimi

Street address

Yas Hospital, Ostad Nejatolahi Ave., Karimkhan Blvd.

City

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Phone

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Email

maeb214@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Vice-Dean of Research of Tehran University of Medical Sciences, Dr. Fotouhi

Street address

Vice-Dean of Research, Tehran University of Medical Sciences, Floor 6, Qods St., Keshavarz Blvd, Tehran, Iran

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1416634793

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vcr@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Mahbod Ebrahimi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Mahbod Ebrahimi

Position

Associate professor

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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
Title and more details about the data/document
All data is potentially shareable after unidentified participants.
When the data will become available and for how long
After the manuscript is published.
To whom data/document is available
No limitations.
Under which criteria data/document could be used
Those who are allowed to request to receive non-identifiable personal data or other documents must have a written proposal (including the type of statistical analysis) and the ethics number. any additional analysis must perform under the corresponding author's supervision.
From where data/document is obtainable
Communicate with the corresponding author via email: maeb214@yahoo.com
What processes are involved for a request to access data/document
Any request must be sent through e-mail and accompanied by a proposal with an ethics code under the supervision of Dr. Ebrahimi.
Comments