# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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**

Tehran

**Province**

Tehran

**Postal code**

1598718311

**Phone**

+98 917 172 1788

**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

**City**

Tehran

**Province**

Tehran

**Postal code**

1416634793

**Phone**

+98 21 8163 3698

**Email**

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

**Street address**

Yas Hospital, Ostad Nejatolahi Ave., Karimkhan Blvd.

**City**

Tehran

**Province**

Tehran

**Postal code**

1598718311

**Phone**

+98 21 4216 0000

**Email**

maeb214@yahoo.com

## Person responsible for scientific 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

**Street address**

Yas Hospital, Ostad Nejatolahi Ave., Karimkhan Blvd.

**City**
Tehran
**Province**
Tehran
**Postal code**
1598718311
**Phone**
+98 21 4216 0000
**Email**
maeb214@yahoo.com

## Person responsible for updating data

**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
**Street address**
Yas Hospital, Ostad Nejatolahi Ave., Karimkhan Blvd.
**City**
Tehran
**Province**
Tehran
**Postal code**
1598718311
**Phone**
+98 21 4216 0000
**Email**
maeb214@yahoo.com

## 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**