

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Comparing the effect of intrauterine injection of platelet-rich plasma on pregnancy outcome in IVF candidate women with recurrent implantation failure and thin endometrium

Protocol summary

Study aim

Comparing the effect of intrauterine injection of platelet-rich plasma on pregnancy outcome in IVF candidate women with recurrent implantation failure and thin endometrium

Design

This controlled, parallel-group, nonblinded, phase 3 clinical trial is conducted on 90 women with recurrent implantation failure and thin endometrium and candidates for IVF.

Settings and conduct

This study is conducted on women who have been referred to Yas Hospital for their IVF and have a history of recurrent implantation failure and thin endometrium. In the intervention group, 24 to 48 hours before embryo transfer, 5 cc of platelet-rich plasma is poured into the uterus using an intrauterine sperm injection (IUI) catheter. However, in the control group, no extra intervention is done.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women aged 20 to 38, with body mass index below 30, having A or B fetuses and endometrial thickness less than 7 mm despite receiving hormonal treatment, as well as a history of IVF failure. Exclusion criteria: patients with a history of underlying disease or uterine disorders.

Intervention groups

In the intervention group, 24 to 48 hours before the embryo transfer, 5 cc of platelet-rich plasma is poured into the uterus using an intrauterine insemination (IUI) catheter. In the control group: Before the embryo transfer, no extra intervention is performed for the patient.

Main outcome variables

Clinical pregnancy is checked once, six weeks after embryo transfer.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240119060732N1**

Registration date: **2024-01-28, 1402/11/08**

Registration timing: **prospective**

Last update: **2024-01-28, 1402/11/08**

Update count: **0**

Registration date

2024-01-28, 1402/11/08

Registrant information

Name

Firoozeh Akbari Asbagh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4216 0852

Email address

fasbagh_md@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-29, 1402/12/10

Expected recruitment end date

2025-02-28, 1403/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of intrauterine injection of platelet-rich plasma on pregnancy outcome in IVF candidate women with recurrent implantation failure and thin endometrium

Public title

Effect of intrauterine injection of platelet-rich plasma on pregnancy outcome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 20 to 38 years Body mass index below 30 Patients with embryo quality A or B Endometrial thickness less than 7 mm despite receiving hormonal treatment With a history of IVF failure

Exclusion criteria:

Patients with diabetes Use of immune system suppressing drugs Patients with malignancy Uterine myomatosis or adenomyosis or hydrosalpingus Endometriosis stage 4 The presence of acute pelvic infection The presence of blood or platelet disorders

Age

From **20 years** old to **38 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

N/A

Randomization description

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

The ethic committee of Tehran University of Medical sciences

Street address

Ethics committee of Tehran University of Medical Sciences, School of Medicine, Tehran Province, Tehran, Pour Sina St" to "Tehran University of Medical Sciences, School of Medicine, Pour Sina St., Qods St.,

Kesahvarz Blvd.

City

Tehran

Province

Tehran

Postal code

1598718311

Approval date

2023-09-30, 1402/07/08

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1402.364

Health conditions studied

1

Description of health condition studied

Female infertility of uterine origin

ICD-10 code

N97.2

ICD-10 code description

Female infertility of uterine origin

Primary outcomes

1

Description

Clinical pregnancy

Timepoint

Once, six weeks after fetal transfer

Method of measurement

Ultrasound

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 24 to 48 hours before the embryo transfer, 5 cc of platelet-rich plasma, which is prepared from the person's peripheral blood, is poured into the uterus using an intrauterine insemination (IUI) catheter.

Category

Treatment - Drugs

2

Description

Control group: Before the embryo transfer, no extra intervention is performed for the patient and the patient returns on the day of the embryo transfer.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yas hospital

Full name of responsible person

Firoozeh Akbari Asbagh

Street address

Yas hospital, Next to the Sarv St., North Nejatollahi St., Karimkhan Ave.

City

Tehran

Province

Tehran

Postal code

1597856511

Phone

+98 21 8608 9089

Email

fasbagh_md@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. Ali Akbari Sari

Street address

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

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

Firoozeh Akbari Asbagh

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Yas hospital, Next to the Sarv St., North Nejatollahi St., Karimkhan Ave.

City

Tehran

Province

Tehran

Postal code

1597856511

Phone

+98 21 4216 0852

Fax**Email**

fasbagh_md@yahoo.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tehran University of Medical Sciences

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+98 21 4216 0852

Fax**Email**

fasbagh_md@yahoo.com

Person responsible for updating data

Contact**Name of organization / entity**

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Province

Tehran

Postal code

1597856511

Phone

+98 21 4216 0852

Fax**Email**

fasbagh_md@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

Not applicable

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

Not applicable

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

The data is only available to the project manager, Dr. Firoozeh Akbari Asbagh, and any analysis must be done with her opinion.

From where data/document is obtainable

The data is only available to the project manager, Dr. Firoozeh Akbari Asbagh, and any analysis must be done with her opinion.

What processes are involved for a request to access data/document

Any request must be sent by e-mail with its proposal to Dr. Firoozeh Akbari Asbagh.

Comments