Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Assessment of the effect of intraovarian platelet-rich plasma (PRP) injection on the results of assisted reproductive methods in infertile women with poor ovarian response (Poseidon 1, 2, 3,4)

Protocol summary

Study aim
Effect of intraovarian injection of platelet-rich plasma (PRP) on ovarian function in infertile women with poor ovarian response

Design
Randomized clinical trial, conducted on 64 eligible patients. Participants were randomly assigned to the intervention or control group using the block randomization method.

Settings and conduct
This prospective, randomized, controlled clinical trial study will be conducted at the Milad Infertility Center, affiliated with Mashhad University of Medical Sciences, on women aged 21 to 42 undergoing IVF cycles. Eligible participants meet the inclusion criteria and provide written informed consent. They will be randomly assigned to two intervention and control groups.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Poor ovarian response based on POSEIDON criteria. Exclusion Criteria: Severe endometriosis (grade 3 or 4), severe adenomyosis, or uterine anomalies and severe male factor infertility

Intervention groups
In the intervention group, 60 cc of blood is collected and PRP is prepared using the Royagen kit (approved by the Ministry of Health) with a 4–5× platelet concentration. Then 1.5–2 cc of PRP is injected into each ovary under anesthesia and ultrasound guidance on days 7–10 of the menstrual cycle. The procedure is repeated in two consecutive cycles, followed by ovarian stimulation with gonadotropins in the third month.In the control group, ovarian stimulation is performed with the same gonadotropin protocol (Gonal-F and HMG), followed by Cetrotide and GnRH agonist trigger as indicated. Oocyte retrieval is performed, and the resulting embryos are cryopreserved. No PRP injection is performed in this group

Main outcome variables
Chemical, Clinical, Ongoing pregnancy rate, and Miscarriage rate

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20181030041503N12**
Registration date: **2026-01-01, 1404/10/11**
Registration timing: **registered_while_recruiting**

Last update: **2026-01-01, 1404/10/11**
Update count: **0**

Registration date
2026-01-01, 1404/10/11

Registrant information

Name
Malihe Mahmoudinia

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3882 9878

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2025-10-23, 1404/08/01

Expected recruitment end date
2027-02-20, 1405/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Assessment of the effect of intraovarian platelet-rich plasma (PRP) injection on the results of assisted reproductive methods in infertile women with poor ovarian response (Poseidon 1, 2, 3,4)

Public title
Effect of intraovarian injection of platelet-rich plasma in women with poor ovarian response
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Women with poor ovarian response, which includes patients who had less than or equal to 4 oocytes retrieved in a previous IVF cycle Anti-Mullerian Hormone (AMH) less than 1.2 ng/mL Antral follicle count (AFC) less than 5 follicles in both ovaries on ultrasound on the third day of the period Regular menstruation every 24-35 days
Exclusion criteria:
Presence of severe endometriosis, grade 3 and 4. Presence of severe adenomyosis. Presence of a uterine anomaly. Presence of a chromosomal abnormality in the karyotype of either the woman or the man. A medical history that includes uncontrolled hypertension, thrombotic disease, or uncontrolled diabetes.
Age
From **21 years** old to **42 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the random allocation sequence of individuals to the study groups was generated using the permuted block method. The random allocation sequence was performed using the Random Allocation Software with a block size of four. The permuted block method is one of the random allocation techniques in which each block is selected to be the size of the number of study groups. For allocation concealment, sealed envelopes were used. Based on the order of entry of the research units, the envelopes were opened sequentially, and the assigned group was revealed.
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 Mashhad university of Medical Sciences
Street address
Imam Reza Hospital, Imam Reza St., Mashhad, Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
9178943791
Approval date
2025-06-07, 1404/03/17
Ethics committee reference number
IR.MUMS.REC.1404.100

Health conditions studied

1

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

Primary outcomes

1

Description
Number of follicles developed
Timepoint
Trigger injection day
Method of measurement
Transvaginal ultrasound

2

Description
Total number of oocytes retrieved on the day of ovulation
Timepoint
On the day of Ovum Pick Up
Method of measurement
Examination by an embryologist

3

Description

Number of grade 1 and 2 embryos

Timepoint

2-5 days after ovulation

Method of measurement

Examination by an embryologist

4

Description

Chemical pregnancy: positive β-HCG test greater than 25 mIU/ml after 12–16 days from embryo transfer

Timepoint

12–16 days after embryo transfer

Method of measurement

Serum β-human chorionic gonadotropin (β-hCG) measurement using quantitative immunoassay

5

Description

Clinical pregnancy rate

Timepoint

6 weeks after transfer

Method of measurement

Ultrasound examination

6

Description

Ongoing Pregnancy Rate

Timepoint

At 12weeks after embryo transfer

Method of measurement

Ultrasound examination

7

Description

Miscarriage rate

Timepoint

Before 20 weeks of pregnancy

Method of measurement

Ultrasound examination

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, 60 cc of blood is collected from each participant, and platelet-rich plasma with a concentration of 4-5 times baseline is prepared using the Royagen kit (approved by the Ministry of Health). Then, 1.5 to 2 cc of PRP is injected into each ovary under anesthesia and ultrasound guidance on days 7 to 10 of the menstrual cycle. The injection is repeated in two consecutive cycles. In the third month, the patient begins ovarian stimulation with gonadotropin drugs at a dose of 225 units of Sinal F and 150 units of HMG on the second day of the cycle. The drug dose is adjusted based on ultrasound findings. When the follicle reaches 14 mm, sterotide is started. When two 16 mm follicles are observed in the ovary, a trigger is performed with a GnRH agonist. Ovulation is performed 36 hours later. Simultaneously with ovulation, PRP is performed in the ovary again. After 3 days, ovarian stimulation with gonadotropin is started again, and the re-stimulation cycle is repeated. And ovulation is performed again.

Category

Treatment - Surgery

2

Description

In the control group, ovarian stimulation is performed with the same gonadotropin protocol (Gonal-F and HMG), followed by Cetrotide and GnRH agonist trigger as indicated. Oocyte retrieval is performed and resulting embryos are cryopreserved. No PRP injection is performed in this group

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Milad Infertility Center, Imam Reza Hospital

Full name of responsible person

Malihe Mahmoudinia

Street address

Milad Infertility Center, Imam Reza Hospital, Daneshgah Street, Mashhad

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen, Tafaghodi

Street address

Vice Chancellor of Research, Mashhad university of Medical sciences, university Avenue, Mashhad

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Tafaghodim@mums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Malihe Mahmoudinia

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

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Milad Infertility Center, Imam Reza Hospital, Daneshgah Street, Mashhad

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Malihe Mahmoudinia

Position
Associate professor

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Person responsible for updating data

Contact

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Full name of responsible person
Malihe Mahmoudinia

Position
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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
I'm looking into the matter

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

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

Analytic Code

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

Data Dictionary

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