Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of Pregnancy Outcomes in Patients with Poor Ovarian Response after Platelet-Rich Plasma (PRP) and Stem Cells Injection; a randomized clinical trial

Protocol summary

Study aim
Comparison of pregnancy outcomes in patients with poor ovarian response after PRP and stem cells injection

Design
The stem cell-treated group, the platelet-rich plasma-treated group, and the untreated (control) group

Settings and conduct
Administration method of PRP and stem cells: Intraovarian injection will be performed in the operating room under conscious sedation within two hours after PRP and stem cell preparation. Based on the patient's study group assignment, either PRP or stem cells will be injected into at least one ovary using a 35-cm 17G single-lumen needle under ultrasound-guided vaginal approach. Although ovaries in advanced maternal age patients with POR may be small and fibrotic, the injection will be achieved by creating new planes within the ovary through dilation and multi-site injections. Patients will be transferred to the recovery room post-procedure and discharged home the same day after 30-40 minutes of observation.

Participants/Inclusion and exclusion criteria
Inclusion: Diagnosis of poor ovarian response (history of one ovulation stimulation cycle with fewer than 4 eggs, AMH below 1.1, and FSH less than 20) Exclusion: Age over 40 years and under 20 years Having at least one of the following conditions: endometriosis, severe oligospermia, hydrosalpinx, kidney disease, liver disease, diabetes, thyroid and autoimmune diseases, history of local allergic reactions, benign intracranial hypertension, history of cancer, patients with fibrocystic breasts and recurrent fibroids and adenomyosis, systemic immune diseases, and chronic inflammation of the endometrium, cervix, and infections

Intervention groups
1. Platelet-rich plasma (PRP) 2. Stem cells 3. No treatment (control) (Due to word limitations, preparation details cannot be included)

Main outcome variables
Chemical Pregnancy (positive serum B-hCG test)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250609066140N1**
Registration date: **2025-07-13, 1404/04/22**
Registration timing: **prospective**

Last update: **2025-07-13, 1404/04/22**
Update count: **0**

Registration date
2025-07-13, 1404/04/22

Registrant information

Name
Mazyar Yousefi hasanalideh

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-08-23, 1404/06/01

Expected recruitment end date
2025-08-23, 1404/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of Pregnancy Outcomes in Patients with Poor Ovarian Response after Platelet-Rich Plasma (PRP) and Stem Cells Injection; a randomized clinical trial

Public title
Comparison of Pregnancy Outcomes in Patients with Poor Ovarian Response after Platelet-Rich Plasma (PRP)and Stem Cells Injection; a randomized clinical trial
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of poor ovarian response (history of one ovulation stimulation cycle with fewer than 4 eggs,Anti-Müllerian Hormone(AMH) below 1.1, and Follicle-stimulating hormone(FSH) less than 20)
Exclusion criteria:
Age over 40 years and under 20 years Having at least one of the following conditions: endometriosis, severe oligospermia, hydrosalpinx, kidney disease, liver disease, diabetes, thyroid and autoimmune diseases, history of local allergic reactions, benign intracranial hypertension, history of cancer, patients with fibrocystic breasts and recurrent fibroids and adenomyosis, systemic immune diseases, and chronic inflammation of the endometrium, cervix, and infections
Age
From **20 years** old to **40 years** old
Gender
Female

Phase
2-3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **105**
Randomization (investigator's opinion)
Randomized
Randomization description
In this randomized clinical trial, block randomization is used to allocate patients into two intervention groups (PRP or stem cell therapy) and a control group. The process is as follows: 1. Homogeneous blocks (e.g., based on age or disease severity) are created. 2. Within each block, allocation sequences (e.g., AABB, ABAB) are randomly predetermined. 3. Each new patient in the block is assigned according to the pre-randomized sequence. This method ensures group balance throughout the study and within each block.
Blinding (investigator's opinion)
Double blinded
Blinding description
The patients' codes and their medication types were computerized and randomly assigned, with each patient receiving a unique envelope code registered in the system. Then, the opaque, numbered envelopes were given to a third party and, after obtaining informed consent, were delivered to the therapist. The study will be conducted in a double-blind manner, meaning neither the patients, the therapist, nor the researchers will be aware of the group assignments
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Alborz University of Medical Sciences
Street address
No. 45, Safarzade St, Golshahr, Karaj
City
Karaj
Province
Alborz
Postal code
7556408591
Approval date
2025-05-24, 1404/03/03
Ethics committee reference number
IR.ABZUMS.REC.1404.061

Health conditions studied

1

Description of health condition studied
Infertility
ICD-10 code
N97.0
ICD-10 code description
Female infertility associated with anovulation

Primary outcomes

1

Description
Positive serum B-Human Chorionic Gonadotropin (hCG) test
Timepoint
4, 8, 12 weeks after intervention
Method of measurement
Electrochemiluminescence immunoassay (ECLIA)

Secondary outcomes

empty

Intervention groups

1

Description
First Intervention Group: Platelet-Rich Plasma (PRP) Recipient GroupThe preparation of PRP (platelet-rich plasma) will involve plasma separation via centrifugation. Approximately 20 mL of blood will be drawn under sterile conditions, and PRP will be prepared using an autologous platelet-rich plasma kit according to the manufacturer's protocol.In summary, after blood collection, the tubes will be centrifuged at 830 × *g* for 8 minutes. A 16-gauge needle attached to a 5-mL syringe will then be inserted into the tube, advancing just above the buffy coat layer. The PRP will be collected by rotating the needle tip. After obtaining approximately 2–4 cc of PRP from the first tube, the second tube will be processed in the same manner (yielding a total of 4–8 cc of PRP). The collected solution will be transferred to a resuspension tube and gently agitated for 30 seconds to 1 minute. The injection protocol will be detailed in the relevant section.

Category
Treatment - Drugs

2

Description
Second Intervention Group: Stem Cell-Treated Group. Preparation and Isolation of Stem Cells:Menstrual blood-derived stem cells (MenSCs) from patients in the treatment group will be collected using sterile menstrual cups on the second day of menstruation. The number of antral follicles will be measured via vaginal ultrasound.The samples will then be placed in collection tubes containing phosphate-buffered saline (PBS) without Ca^{2+} or Mg^{2+} (GMP-grade), supplemented with:100 µg/mL streptomycin,2.5 mg/mL amphotericin B (Fungizone),100 U/mL penicillin, and0.5 mg/mL EDTA.The samples will be immediately transferred to a Class B cleanroom for mesenchymal stem cell (MSC) isolation and culture. The injection protocol will be detailed in the relevant section.

Category
Treatment - Drugs

3

Description
Control group: observation (no treatment)

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Kamali Hospital

Full name of responsible person
Mina Ataee

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Alborz 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
Alborz University of Medical Sciences

Full name of responsible person
Mina Ataee

Position
Associate professor
Latest degree
Specialist
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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
No further information is available.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not 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