# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Investigation of the Effect of Platelet-Rich Plasma (PRP) Injection into the Ovary on Improving Ovarian Response and Oocyte Quality in Patients with Poor Ovarian Response

## Protocol summary

**Study aim**

To determine the effect of intraovarian platelet-rich plasma injection on ovarian response in women with poor ovarian response

**Design**

Prospective, randomized, double-blind, placebo-controlled, parallel-group, single-center clinical trial involving 200 participants.

**Settings and conduct**

This study will be conducted at Fatemeh Zahra Infertility Center in Babol. The intervention group will receive a single 1–2 mL intraovarian injection of platelet-rich plasma, while the control group will receive the same volume of sterile normal saline under transvaginal ultrasound guidance. The injection team will be aware of group allocation, whereas participants, outcome assessors, and the data analyst will be blinded.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: Women aged 30–45 years with poor ovarian response according to the Bologna criteria, no pregnancy during the previous 12 months, a body mass index of 18–30 kg/m², and willingness to provide written informed consent. Exclusion criteria: Conditions that may increase the risk of the intervention or interfere with treatment or study outcomes, including autoimmune or coagulation disorders, active infection, malignancy, current pregnancy, use of potentially interfering medications such as long-term corticosteroids, previous ovarian surgery, or any medical condition that makes intraovarian injection or continuation of infertility treatment inappropriate.

**Intervention groups**

The intervention group will receive a single intraovarian injection of 1–2 mL of platelet-rich plasma into the cortex of each ovary. The control group will undergo the same injection procedure and receive 1–2 mL of sterile normal saline. The injection will be performed under local anesthesia with transvaginal ultrasound guidance. Participants will be observed for 30 minutes after the procedure.

**Main outcome variables**

Number of retrieved oocytes per participant

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20260906070941N1**
Registration date: **2026-09-14, 1405/06/23**
Registration timing: **prospective**

Last update: **2026-09-14, 1405/06/23**
Update count: **0**

**Registration date**

2026-09-14, 1405/06/23

**Registrant information**

**Name**

Seyedeh Mahboobeh Mirtabar

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 11 3232 0960

**Email address**

m.mirtabar@mubabol.ac.ir

**Recruitment status**

**recruiting**

**Funding source**

**Expected recruitment start date**

2026-09-23, 1405/07/01

**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**
Investigation of the Effect of Platelet-Rich Plasma (PRP) Injection into the Ovary on Improving Ovarian Response and Oocyte Quality in Patients with Poor Ovarian Response

**Public title**
Effect of Intraovarian Platelet-Rich Plasma Injection in Women with Poor Ovarian Response
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Women aged 30–45 years. With poor ovarian response (POR) according to the Bologna criteria. No pregnancy during the previous 12 months. Body mass index (BMI) 18–30 kg/m² Written informed consent
**Exclusion criteria:**
Autoimmune diseases such as lupus Known coagulation disorders or clinically significant platelet disorders Active infection at the time of intervention Active malignancy or a history of clinically relevant cancer Current pregnancy Use of medications that may substantially interfere with the intervention, including long-term corticosteroid therapy Previous ovarian surgery Any medical condition considered by the treating physician to make intraovarian injection or continuation of infertility treatment inappropriate.
**Age**
From **30 years** old to **45 years** old
**Gender**
Female

**Phase**
N/A
**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **200**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Eligible participants will be randomly assigned individually to either the intervention or control group in a 1:1 ratio. Block randomization with fixed blocks of four will be used to maintain a balanced allocation between the two groups throughout the recruitment period. No stratification will be used. The randomization sequence will be generated using a computer-generated randomization procedure by an independent researcher who will have no involvement in participant recruitment, administration of the intervention, outcome assessment, or data analysis. The sequence will consist of randomly ordered intervention and control assignments within blocks of four. Allocation concealment will be maintained using sequentially numbered, opaque, sealed envelopes prepared by a researcher who is independent of the recruitment and assessment processes. After a participant meets all eligibility criteria and provides written informed consent, the next envelope in sequence will be opened to determine the assigned group. Thus, the allocation sequence will not be accessible to the investigators responsible for participant recruitment or baseline assessment before assignment.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
In this trial, participants and outcome assessors will be blinded to participants' group allocation. The data analyst will also remain blinded to group allocation until the statistical analysis has been completed and the data have been finalized. To maintain participant blinding, participants in the control group will undergo the same transvaginal, ultrasound-guided intraovarian injection procedure as those in the intervention group under sterile conditions. However, sterile saline will be injected instead of platelet-rich plasma. Thus, the procedure and its appearance will be similar in both groups, and participants will not be informed about the substance injected or their group allocation. The physician or members of the healthcare team performing the injection will be aware of the group allocation because this information is necessary to administer the assigned intervention correctly. However, these individuals will not participate in outcome assessment or data analysis. Outcome assessors and data collectors will, as far as possible, remain blinded to participants' group allocation, and information regarding the type of intervention will not be made available to them. Data analysis will be performed by an analyst who will not have access to group allocation before the statistical analysis is completed. The principal investigator will remain blinded to participants' group allocation during participant allocation and intervention procedures whenever knowledge of the assigned intervention is not necessary. If knowledge of group allocation is required to ensure the correct implementation of the intervention, this information will be available only to the personnel responsible for administering the intervention. The results will be reported and the manuscript will be prepared using coded data. Whenever possible, the manuscript writers will remain unaware of the identity of the study groups until the statistical analysis has been finalized.
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Research Ethics Committees of Health Research Institute - Babol University of Medical Sciences

**Street address**
Babol University of Medical Sciences, Ganj Afroz Ave, Babol

**City**
Babol

**Province**
Mazandaran

**Postal code**
4717647745

**Approval date**
2026-07-19, 1405/04/28

**Ethics committee reference number**
IR.MUBABOL.HRI.REC.1405.153

## Health conditions studied

### 1

**Description of health condition studied**
Poor ovarian response

**ICD-10 code**
N97.9

**ICD-10 code description**
Female infertility

## Primary outcomes

### 1

**Description**
Number of retrieved oocytes per participant at the end of controlled ovarian stimulation

**Timepoint**
At the end of controlled ovarian stimulation, during oocyte retrieval

**Method of measurement**
The number of retrieved oocytes will be determined by direct counting of the oocytes collected during the oocyte retrieval procedure by the embryology laboratory.

## Secondary outcomes

### 1

**Description**
Number of mature oocytes, defined as the number of retrieved oocytes at the metaphase II stage

**Timepoint**
At the time of oocyte retrieval and assessment of oocyte maturity

**Method of measurement**
Mature oocytes will be identified by embryologists based on their metaphase II stage and recorded as the total number of mature oocytes for each participant

### 2

**Description**
Quality of day-three embryos based on standard morphological assessment of cleavage-stage embryos

**Timepoint**
On day 3 after fertilization

**Method of measurement**
Embryo quality will be assessed by an embryologist using standard morphological criteria for cleavage-stage embryos, including cell number, degree of fragmentation, cell symmetry, and other relevant morphological characteristics. The Gardner grading system will not be used.

### 3

**Description**
Blastocyst quality on day 5 or 6, assessed using the Gardner morphological grading system

**Timepoint**
On day 5 or 6 after fertilization, among embryos that develop to the blastocyst stage.

**Method of measurement**
Blastocyst quality will be assessed by an embryologist using the Gardner morphological grading system. Blastocyst expansion, inner cell mass quality, and trophectoderm quality will be graded separately.

### 4

**Description**
Health-related quality of life measured using the validated Persian version of the 36-Item Short Form Health Survey, Second Version

**Timepoint**
At baseline, before intraovarian injection, and 12 weeks after intraovarian injection, before initiation of controlled ovarian stimulation.

**Method of measurement**
Health-related quality of life will be assessed using the validated Persian version of the 36-Item Short Form Health Survey, Second Version. The questionnaire assesses eight health dimensions. Each dimension is scored from 0 to 100, with higher scores indicating better health-related quality of life.

### 5

**Description**
Pain intensity after intraovarian injection, measured on a 0–10 Visual Analogue Scale

**Timepoint**
Immediately after the procedure and during the early post-intervention period

**Method of measurement**
Pain intensity will be assessed using a 0–10 Visual Analogue Scale, where 0 indicates no pain and 10 indicates the most

**6**

**Description**
Occurrence of adverse events related to the intraovarian injection procedure, including bleeding, infection, fever, pelvic or abdominal pain, menstrual changes, and other unexpected complications

**Timepoint**
During the intervention and throughout the post-intervention follow-up period

**Method of measurement**
Adverse events will be assessed through clinical examination, participant reporting, medical record review, and transvaginal ultrasound when clinically indicated.

## Intervention groups

**1**

**Description**
Intervention group: Participants will receive an intraovarian injection of 1–2 mL of autologous platelet-rich plasma into the cortex of each ovary. Platelet-rich plasma will be prepared from 20 mL of the participant's venous blood collected in citrate-containing tubes. The sample will be centrifuged for 10 minutes at 1,500 × g and then for 10 minutes at 2,500 × g. The injection will be performed once under local anesthesia using transvaginal ultrasound guidance with a 7–12 MHz probe through transvaginal puncture by a gynecologist and infertility fellow. Participants will be monitored for 30 minutes after the procedure.

**Category**
N/A

**2**

**Description**
Control group: Participants will receive an intraovarian injection of 1–2 mL of sterile normal saline into the cortex of each ovary. The injection will be performed once under local anesthesia using transvaginal ultrasound guidance with a 7–12 MHz probe through transvaginal puncture by a gynecologist and infertility fellow. Participants will be monitored for 30 minutes after the procedure.

**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Babol University of Medical Sciences

**Full name of responsible person**
Fatemeh Amirkhanloo

**Street address**
Babol University of Medical Sciences, Ganj Afroz Ave, Babol

**City**
Babol

**Province**
Mazandaran

**Postal code**
47176-47745

**Phone**
+98 11 3219 9592

**Email**
dr.f.amirkhanloo83@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Babol University of Medical Sciences

**Full name of responsible person**
Dr. Reza Ghadimi

**Street address**
Babol University of Medical Sciences, Ganj Afroz Ave, Babol

**City**
Babol

**Province**
Mazandaran

**Postal code**
4717647745

**Phone**
+98 911 315 8440

**Email**
rezaghadimi@yahoo.com

**Grant name**
Babol University of Medical Sciences

**Grant code / Reference number**

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

**Title of funding source**
Babol 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**
Babol University of Medical Sciences

**Full name of responsible person**
Fatemeh Amirkhanloo

**Position**
Assistant professor

**Latest degree**
Subspecialist
**Other areas of specialty/work**
Gynecology and Obstetrics
**Street address**
Babol University of Medical Sciences, Ganj Afroz Ave, Babol
**City**
Babol
**Province**
Mazandaran
**Postal code**
4717647745
**Phone**
+98 11 3223 8301
**Email**
dr.f.amirkhanloo83@gmail.com

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Babol University of Medical Sciences
**Full name of responsible person**
Fatemeh Amirkhanloo
**Position**
Assistant professor
**Latest degree**
Subspecialist
**Other areas of specialty/work**
Gynecology and Obstetrics
**Street address**
Babol University of Medical Sciences, Ganj Afroz Ave, Babol
**City**
Babol
**Province**
Mazandaran
**Postal code**
4717647745
**Phone**
+98 11 3223 8301
**Email**
dr.f.amirkhanloo83@gmail.com

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Babol University of Medical Sciences
**Full name of responsible person**
Fatemeh Amirkhanloo
**Position**
Assistant professor
**Latest degree**
Subspecialist
**Other areas of specialty/work**
Reproductive Biology
**Street address**
Babol University of Medical Sciences, Ganj Afroz Ave, Babol
**City**
Babol
**Province**
Mazandaran
**Postal code**
471355475
**Phone**
+98 11 3227 4881
**Email**
dr.f.amirkhanloo83@gmail.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**
Yes - There is a plan to make this available
**Informed Consent Form**
Yes - There is a plan to make this available
**Clinical Study Report**
No - There is not a plan to make this available
**Analytic Code**
Yes - There is a plan to make this available
**Data Dictionary**
Yes - There is a plan to make this available
**Title and more details about the data/document**
Deidentified Individual Participant Data (IPD) – This includes all deidentified participant data related to primary and secondary outcome measures, collected through questionnaires and clinical records. Study Protocol – Full finalized protocol submitted to the ethics committee. Statistical Analysis Plan (SAP) – Final version describing the statistical methods used for primary and secondary outcomes. Informed Consent Form – Blank version of the informed consent form used for participant enrollment. Analytic Code – R/Stata/SPSS scripts used for statistical analysis. Data Dictionary – A detailed guide to the variables, definitions, formats, and codes used in the dataset
**When the data will become available and for how long**
The documents and data files will be available starting 6 months after the main publication and will remain accessible for at least 5 years.
**To whom data/document is available**
Data and documents will be made available to researchers affiliated with academic or nonprofit institutions, with a clear and valid research purpose. Requests from commercial entities may be considered case-by-case.
**Under which criteria data/document could be used**
Data/documents can be used only for secondary analyses related to reproductive health, fertility, or public health. Proposals will be reviewed by the principal investigator and research ethics coordinator. Data will be shared via secure data transfer.
**From where data/document is obtainable**
Requests should be directed via email to: Dr. Fatemeh Bakouei Babol University of Medical Sciences Email:dr.f.amirkhanloo83@gmail.com

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

Interested researchers should submit: A short proposal (max 1 page) Ethics approval (if applicable) Signed data use agreement Requests will be reviewed within 2–4 weeks. Access will be granted after approval and agreement signature.

**Comments**

None at this time.