# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## Evaluation of the effect of platelet-rich plasma injection in an ovary in cases of poor ovarian function (poor response)

## Protocol summary

**Study aim**

The purpose of this study; The effect of PRP (enriched platelet) injection into one of the ovaries and its comparison with other ovaries in women with poor ovarian response.

**Design**

A clinical trial with the control group, with parallel, non-random, phase 4 groups on 12 patients.

**Settings and conduct**

In 12 patients with ovarian dysfunction referred to Valiasr Infertility Clinic, ovarian stimulation begins with ovulation-stimulating drugs, and immediately after the follicle reaches 17 mm, the egg is removed at the same time; 4 ccs of enriched platelets (PRP) are injected into one ovary at four points under anesthesia and then in vitro fertilization (IVF) is performed. PRP is not performed in the other ovary (control).

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: Women with a history of poor ovarian function and normal sperm analysis Exclusion criteria: hematological diseases; chromosomal or genetic disorders; Uterine disorders; Hemoglobin level less than 11 grams per deciliter and platelets less than one hundred and fifty thousand cubic millimeters; Systemic use of corticosteroids within two weeks before the procedure.

**Intervention groups**

Intervention group: 12 patients with the poor ovarian function will be included in the study and will be stimulated to ovulate. Then when the follicle reaches 17 mm at the same time as the metaphase 2 egg is picked up; 4 ccs of platelet-rich plasma is injected at four points in an ovary under anesthesia by the Unit Infertility Fellowship. Control group: The ovaries of the same 12 patients with poor ovarian function in which the ovaries do not inject platelet-rich plasma.

**Main outcome variables**

The number of oocytes; Number of mature oocytes ; Antimullerian hormone levels; Follicle-stimulating hormone (FSH) levels.

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20210828052310N1**
Registration date: **2021-10-02, 1400/07/10**
Registration timing: **prospective**

Last update: **2021-10-02, 1400/07/10**
Update count: **0**

**Registration date**

2021-10-02, 1400/07/10

**Registrant information**

**Name**

Saeedeh Shahsavari

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2021-10-19, 1400/07/27

**Expected recruitment end date**

2022-10-19, 1401/07/27

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**
Evaluation of the effect of platelet-rich plasma injection in an ovary in cases of poor ovarian function (poor response)

**Public title**
Impact of platelet-rich plasma on an ovary in cases of poor ovarian function

**Purpose**
Treatment

**Inclusion/Exclusion criteria**
**Inclusion criteria:**
History of less than 3 eggs per cycle Antimullerian hormone less than 0.5 Antral follicles less than 5 Existence of 10 million sperm in sperm analysis At least three percent of normal sperm morphology
**Exclusion criteria:**
Immunological diseases of patients Hematologic disease Chromosomal or genetic disorder Hemoglobin level less than 11 grams per deciliter and platelets less than one hundred and fifty thousand per cubic millimeter Systemic use of corticosteroids within two weeks before the procedure Absence of underlying disease of infertile women No contraindications for pregnancy Uterine disorders Submucosal myoma Asherman syndrome

**Age**
From **18 years** old to **45 years** old

**Gender**
Female

**Phase**
3

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **12**

**Randomization (investigator's opinion)**
Not randomized

**Randomization description**

**Blinding (investigator's opinion)**
Not blinded

**Blinding description**

**Placebo**
Not used

**Assignment**
Single

**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**
**Name of ethics committee**
Ethics committee of Tehran University of Medical Sciences
**Street address**
Imam Khomeini Hospital Complex,East Bagherkhan street.
**City**
Tehran
**Province**
Tehran
**Postal code**
1419733141

**Approval date**
2021-08-04, 1400/05/13

**Ethics committee reference number**
IR.TUMS.IKHC.REC.1400.191

## Health conditions studied

**1**

**Description of health condition studied**
Poor Ovarian Response

**ICD-10 code**
N97

**ICD-10 code description**
Female infertility

## Primary outcomes

**1**

**Description**
Number of Oocyte in the first and second cycles.

**Timepoint**
The oocyte retrieval day

**Method of measurement**
Based on embryologist assessment

**2**

**Description**
Number of mature oocyte

**Timepoint**
The oocyte retrieval day in the first and second cycles.

**Method of measurement**
Based on embryologist assessment

**3**

**Description**
Anti Mullerian Hormone level

**Timepoint**
The second day of cycles 1 and 2

**Method of measurement**
Blood test

**4**

**Description**
Follicle Stimulating Hormone level.

**Timepoint**
The second day of cycles 1 and 2

**Method of measurement**
Blood test

## Secondary outcomes

### 1

**Description**
Number of Embryo
**Timepoint**
Three to six days after fertilization
**Method of measurement**
Based on the opinion of the embryologist

## Intervention groups

### 1

**Description**
Intervention group: 12 patients with poor ovarian function referred to Valiasr Infertility Clinic will participate in the study during the year 1400. The ovulation stimulation is done by prescribing Dofaston 10 mg twice a day from the day of 2-3 menstrual cycles to the day of ovulation. Then when the follicle reaches 17 mm at the same time as the oocyte of metaphase two is removed; 4 ccs of platelet-rich plasma is injected at four points of the ovary under anesthesia by the infertility unit.
**Category**
Treatment - Drugs

### 2

**Description**
Control group: On the opposite side of the ovary, the same twelve patients with poor ovarian function do not inject platelet-rich plasma.
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Imam Khomeini Hospital Complex,Vali-Asr Infertility Clinic.
**Full name of responsible person**
Saeideh Shahsavari
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## Sponsors / Funding sources

### 1

**Sponsor**
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Tehran University of Medical Sciences
**Full name of responsible person**
Mohammad Ali Sahraian
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6th floor, Ghods St, Keshavarz Blvd.Central Organization of the University, Deputy of Research and Technology of Tehran University of Medical Sciences.
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**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
No
**Title of funding source**
Deputy of Research and Technology of 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**
Bandare-abbas University of Medical Sciences
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Assistant Professor
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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**
patients privacy
**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