

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### Evaluation of the effect of intraovarian platelet rich plasma injection on ovarian folliculogenesis and intracytoplasmic sperm injection outcome in poor responders- Quasi-Experimental Study

#### Protocol summary

##### Study aim

The purpose of this study is to investigate the effectiveness of intraovarian platelet-rich plasma injection on ovarian folliculogenesis and the results of intracytoplasmic sperm injection.

##### Design

In Quasi-Experimental study with a before-and-after design, 20 patients with poor ovarian response will be enrolled in a single group in the period of 2024-2025 at Mehr medical Institute. Blinding and randomization are not valid in this study.

##### Settings and conduct

The present study will be conducted at Mehr Medical Institute. Pituitary suppression will be done using the agonist method. Ovarian follicles will be obtained using vaginal ultrasound. Platelet rich plasma will be prepared according to the instructions. After oocyte retrieval, 1.5 ml of PRP will be injected into each ovary using a G17, 35 cm single lumen needle and guided by ultrasound. In the third menstrual cycle after PRP treatment, all participants will receive the GnRH agonist protocol and undergo a second cycle of ICSI.

##### Participants/Inclusion and exclusion criteria

Patients with poor ovarian reserve Inclusion criteria: Age less than 40 years- The number of antral follicles less than 5- Anti-Müllerian hormone level less than 0.3 nano-grams/milliliter- Exclusion criteria: Women with autoimmune disorders- Anemia- Thrombophilic disorders- Current cancer or medical history of cancer- Severe male infertility- Endometriosis

##### Intervention groups

After oocyte retrieval, 1.5 ml of platelet-rich plasma will be injected into each ovary under ultrasound guidance.

##### Main outcome variables

The total number of oocytes retrieved- The total number of metaphase II oocytes

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180528039878N5**

Registration date: **2024-03-04, 1402/12/14**

Registration timing: **prospective**

Last update: **2024-03-04, 1402/12/14**

Update count: **0**

##### Registration date

2024-03-04, 1402/12/14

##### Registrant information

##### Name

Marzieh Mehrafza

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 3376 4270

##### Email address

dr.Mehrafza@mehrinstitute.org

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-05-21, 1403/03/01

##### 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**

Evaluation of the effect of intraovarian platelet rich plasma injection on ovarian folliculogenesis and intracytoplasmic sperm injection outcome in poor responders- Quasi-Experimental Study

**Public title**

PRP effect on ovary

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age less than 40 years The number of antral follicles is less than 5 Anti-Müllerian hormone level less than 0.3 nano-grams/milliliter

**Exclusion criteria:**

Women with autoimmune disorders Anemia Thrombophilic disorders Current cancer or medical history of cancer Severe male infertility Endometriosis

**Age**

From **18 years** old to **40 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **20**

**Randomization (investigator's opinion)**

N/A

**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 Guilan University of Medical Sciences

**Street address**

Mehr Medical Institute, Irshad St, Shahid Ansari BLvd, Rasht

**City**

Rasht

**Province**

Guilan

**Postal code**

417861311

**Approval date**

2024-02-14, 1402/11/25

**Ethics committee reference number**

IR.GUMS.REC.1402.584

**Health conditions studied****1****Description of health condition studied**

Primary ovarian failure

**ICD-10 code**

E28.3

**ICD-10 code description**

Primary ovarian failure

**Primary outcomes****1****Description**

The total number of oocytes retrieved

**Timepoint**

The day of ovarian puncture before platelet rich plasma injection, The day of ovarian puncture after platelet rich plasma injection

**Method of measurement**

According to the count

**2****Description**

The total number of metaphase II oocytes

**Timepoint**

The day of ovarian puncture before platelet rich plasma injection, The day of ovarian puncture after platelet rich plasma injection

**Method of measurement**

According to the count

**Secondary outcomes****1****Description**

Basal level of Anti-Müllerian Hormone

**Timepoint**

Serum level on the third day of the menstrual cycle before platelet-rich plasma injection, Serum level on the third day of the menstrual cycle after platelet-rich plasma injection

**Method of measurement**

Using the test kit

**2****Description**

Number of embryos

**Timepoint**

In the cycle before platelet-rich plasma injection, In the cycle after platelet-rich plasma injection

**Method of measurement**

According to the count

## Intervention groups

1

### Description

Intervention group: Intraovarian injection of platelet-rich plasma - 8.5 ml of peripheral venous blood will be drawn into a 10 ml syringe containing 1.5 ml of anticoagulant solution. According to the instructions of the kit (Royagen, Iran), 3 ml of lympho-plasma platelet-rich with a platelet concentration 4 to 5 times higher than the base blood and 2000 lymphocytes per microliter will be prepared.

### Category

Treatment - Other

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Mehr Medical Institute

#### Full name of responsible person

Marzieh Mehrafza

#### Street address

Mehr Medical Institute, Irshad St., Shahid Ansari Blvd

#### City

Rasht

#### Province

Guilan

#### Postal code

4178613111

#### Phone

+98 13 3376 4270

#### Fax

+98 13 3375 4257

#### Email

marzieh.mehrafza@gmail.com

#### Web page address

<http://www.mehrinstitute.org/>

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Mehr Medical Institute

#### Full name of responsible person

Marzieh Mehrafza

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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

Mehr Medical Institute

#### Proportion provided by this source

100

#### Public or private sector

Private

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

*empty*

#### Country of origin

#### Type of organization providing the funding

Other

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Mehr Medical Institute

#### Full name of responsible person

Marzieh Mehrafza

#### Position

Non-faculty subspecialist M.D

#### Latest degree

Subspecialist

#### Other areas of specialty/work

Gynecology and Obstetrics

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Mehr Medical Institute

**Full name of responsible person**

Marzieh Mehrafza

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Mehr Medical Institute

**Full name of responsible person**

Marzieh Mehrafza

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

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

**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