# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Comparison of the effect of intraovarian injection of Plasma Rich Growth Factor (PRGF) and Plasma Rich Platelate (PRP) on improving the response and pregnancy outcomes in women undergoing IVF with poor ovarian response

## Protocol summary

**Study aim**

The effect of intraovarian injection of plasma rich growth factor(PRGF) on improving the response and pregnancy outcomes in women undergoing IVF with poor ovarian response

**Design**

The clinical trial consisted of prp intraovarian injection sample group and prgf control group, double-blind, randomized, phase 2 on 30 patients. Excel software rand function was used for randomization.

**Settings and conduct**

Ovarian stimulation will be done on day 3 of the menstrual cycle. When the follicles are about 14 mm in diameter, the GnRH antagonist begins. When at least three follicles more than 17 mm in diameter are observed in the ovaries, ovulation induction will be performed using 10,000 IU of human chorionic gonadotropin (hCG).The eggs will be aspirated 36 hours after hCG administration. On the day of ovulation after an ovarian puncture, 3 cc of PRGF/PRP will be injected into each ovary. In the third menstrual cycle after checking the serum levels of FSH, AMH, patients will be undertaken again the ovulation stimulation cycle. Finally, outcom of pregnancies will be assessed in both groups.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: Women under 42 years of age with a history of low ovarian reserve (less than 3 eggs in previous IVF cycle or abnormal laboratory tests)
Exclusion criteria: Women with anemia, history of malignancy, any endocrine disorders (hypothyroidism, hyperprolactinemia)

**Intervention groups**

In the intervention group, 3 cc of PRGF is injected during ovulation and in the control group, 3 cc of PRP is injected during ovulation.

**Main outcome variables**

clinical pregnancy

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20160722029027N12**
Registration date: **2022-05-14, 1401/02/24**
Registration timing: **registered_while_recruiting**

Last update: **2022-05-14, 1401/02/24**
Update count: **0**

**Registration date**

2022-05-14, 1401/02/24

**Registrant information**

**Name**
Leila Nazari
**Name of organization / entity**
Shahid Beheshti University of Medical Sciences
**Country**
Iran (Islamic Republic of)
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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2022-05-10, 1401/02/20

**Expected recruitment end date**

2022-12-11, 1401/09/20

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effect of intraovarian injection of Plasma Rich Growth Factor (PRGF) and Plasma Rich Platelate (PRP) on improving the response and pregnancy outcomes in women undergoing IVF with poor ovarian response

**Public title**

Comparison of the effect of intraovarian injection of PRGF and PRP on improving the response and pregnancy outcomes

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Women under the age of 42 Having a history of low ovarian reserve (less than 3 eggs in the previous IVF cycle) Abnormal laboratory tests anti mulerian hormone fewer than 1.1ng /dl Counting antral follicles 5-7 on transvaginal sonography

**Exclusion criteria:**

Women with anemia diagnosis history of malignancy Any endocrine disorders (hypothyroidism, hyperprolactinemia)

**Age**

To **42 years** old

**Gender**

Female

**Phase**

2

**Groups that have been masked**

- Participant
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization will be done by generating random numbers in Excel software. 1. In a column of Excel we enter 25 samples in each group. 2. In the next column we generate random numbers using the following command: RAND 3. After sorting the generated random numbers, a random list will be generated according to which people will be assigned to two groups.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Blindness will be such that the patient will not know what treatment she will receive. Also, the researcher who records the results will not be aware of the type of treatment applied to the patient.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Shahid Beheshti University of Medical Sciences

**Street address**

Velenjak, Yaman St, Chamran highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1983969411

**Approval date**

2022-03-06, 1400/12/15

**Ethics committee reference number**

IR.SBMU.REC.1400.026

## Health conditions studied

### 1

**Description of health condition studied**

patient with diminished ovarian reserve

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**

The rate of clinical pregnancy in the two groups undergoing PRGF and the PRP

**Timepoint**

4 week after embryo transfer

**Method of measurement**

By seeing the fetal heartbeat on ultrasound

## Secondary outcomes

### 1

**Description**

The number of retrieved oocytes in the two groups injected with PRGF and PRP

**Timepoint**

During ovarian puncture

**Method of measurement**

counting

## Intervention groups

### 1

**Description**
In the intervention group, 1:35 cc of blood is taken from women. The blood sample is centrifuged at 1200 rpm for 12 minutes to separate the red blood cells. The extracted plasma is centrifuged at 3500 rpm for 7 minutes. Three cc of plasma remains in each tube, which is injected into the ovary through the vagina within 20 minutes after preparation for injection with a special ovulation needle.
**Category**
Treatment - Surgery

### 2

**Description**
In intervention group 2: first,1.5 cc of platelet activating factor made by the company (Aria based on diagnosis) will be added to 3 cc of platelet-rich plasma and after 20 minutes, two phases will be created in plasma preparation. A portion of platelet debris will be formed at the top and a portion of growth factor-rich plasma at the bottom. In the last step, it will be centrifuged for 4 minutes at 4000 rpm. The supernatant is then drawn with a needle and the sample will be taken with an ovulation needle through the ovary
**Category**
Treatment - Surgery

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Infertility and IVF unit of Talghani hospital
**Full name of responsible person**
Leila Nazari
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Yaman St, Velenjak, Chamran highway
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
Afshin Zarghi
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Zarghi@sbmu.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Shahid Beheshti 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**
Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
Zahra Razghandi
**Position**
Infertility Fellowship
**Latest degree**
Specialist
**Other areas of specialty/work**
Gynecology and Obstetrics
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## 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**
Yes - There is 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**
Only information about the main outcome, including chemical pregnancy, clinical pregnancy, ongoing pregnancy, abortion rate, and possible complications from the intervention, can be shared.
**When the data will become available and for how long**
Without restriction
**To whom data/document is available**
All researchers
**Under which criteria data/document could be used**
With permission from the responsible authorEmail to the responsible author
**From where data/document is obtainable**
Email to the responsible author
**What processes are involved for a request to access data/document**
Email to the responsible author
**Comments**