

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Comparison of the effect of intraovarian injection of Plasma Rich Growth Factor (PRGF) and Plasma Rich Platelet (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, outcome 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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+98 21 2271 8000

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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 Platelet (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

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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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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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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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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 author
Email 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**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Zahra Razghandi

Position

Medical doctor

Latest degree

Specialist

Other areas of specialty/work

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