

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 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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+98 76 3333 3280

Email address

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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

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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

Street address

Vali-Asr Infertility Clinic, Imam Khomeini Hospital Complex, Keshavarz Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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

Full name of responsible person

Saeide Shahsavari

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Researcher

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Master

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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