

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

A comparison of the effect of intraovarian injection of autologous platelet rich plasma (PRP) versus PRP plus gonadotropin and gonadotropin alone on ovarian rejuvenation in patients with diminished ovarian reserve

Protocol summary

Study aim

The aim of this study is to compare the effect three treatment methods including gonadotropin, gonadotropin plus intraovarian injection of autologous platelet rich plasma (PRP) and PRP alone on increasing ovarian reserve.

Design

In a randomized, not-blinded, phase 2 clinical trial, without control group and using a parallel group design, 45 infertile women with diminished ovarian reserve will randomly assign into three groups of gonadotropin , PRP plus gonadotropin and PRP alone. Randomization will be performed using G power software.

Settings and conduct

This study will perform on randomized assigned 3 groups of infertile women with diminished ovarian reserve at Yazd Research and Clinical Center for infertility.

Participants/Inclusion and exclusion criteria

Include criteria: Age 20 to48 years Diminish ovarian reserve (AMH <1.1 ,AFC<5) Women with a history of at least one IVF failure Exclude criteria: Male factor Tubal factor Polycystic Ovarian Syndrome

Intervention groups

The patients are Randomly assigned to one of the three groups of gonadotropin injection, both gonadotropin plus intraovarian injection of PRP ,and intraovarian injection of PRP alone.

Main outcome variables

Increasing AMH level; Increasing AFC; Occurrence of spontaneous pregnancy

General information

Reason for update

Changing the recruitment start date

Acronym

IRCT registration information

IRCT registration number: **IRCT20151013024512N7**

Registration date: **2021-02-11, 1399/11/23**

Registration timing: **prospective**

Last update: **2021-11-29, 1400/09/08**

Update count: **2**

Registration date

2021-02-11, 1399/11/23

Registrant information

Name

Abbas Aflatoonian

Name of organization / entity

Yazd research and clinical center for infertility

Country

Iran (Islamic Republic of)

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+98 358247085

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-15, 1399/11/27

Expected recruitment end date

2021-05-04, 1400/02/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of the effect of intraovarian injection of autologous platelet rich plasma (PRP) versus PRP plus

gonadotropin and gonadotropin alone on ovarian rejuvenation in patients with diminished ovarian reserve

Public title

Comparison of the effect of PRP versus PRP plus gonadotropin and gonadotropin alone on ovarian rejuvenation in patients with diminished ovarian reserve

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Female infertility Diminish ovarian reserve (AMH<1.1 and AFC< 5-7) 20 to 48 years

Exclusion criteria:

Uterin anomaly Polycystic Ovarian Syndrome Male factor Tubal factor

Age

From **20 years** old to **48 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

45 infertile women with diminished ovarian reserve who are referred for infertility treatment will be allocated into three interventional groups via simple, individual randomization method using the table of random numbers. Randomization was previously performed for 45 cases into three groups. This is a not-blinded study. Therefore, the clinician will consecutively assign each woman with the inclusion criteria into one of the three intervention groups for receiving the specific intervention for each group

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of Yazd Reproductive Sciences Institute, Yazd Shahid Sadoughi University of Med

Street address

Bouali Ave, Safaiyeh, Reproductive Sciences Institute

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8916877391

Approval date

2020-07-19, 1399/04/29

Ethics committee reference number

IR.SSU.RSI.REC.1399.025

Health conditions studied

1

Description of health condition studied

Ovarian rejuvenation in diminished ovarian reserve patients

ICD-10 code

E28.3

ICD-10 code description

Primary ovarian failure

Primary outcomes

1

Description

Increase Anti-Müllerian hormone level

Timepoint

At the beginning of the study, every month up to 3 months

Method of measurement

Lab Test

Secondary outcomes

1

Description

Antral follicular count

Timepoint

1 to 4 months later

Method of measurement

Transvaginal sonography

2

Description

Spontaneous pregnancy

Timepoint

3 months later

Method of measurement

Lab test

3

Description

Entering assisted reproductive cycle

Timepoint

Once the AMH increases or the patient insists on doing assisted reproductive cycle

Method of measurement

Lab test

Intervention groups**1****Description**

Frist intervention group: 15 infertile women with diminished ovarian reserve aged between 20-48 years were administered by gonadotropin (Cinnal f, 75 IU, CinnaGen Co.) with the dose of 75IU, 1 ampule in each ovary between day 10-14 menstrual cycles.

Category

Treatment - Drugs

2**Description**

Second intervention group: 15 infertile women with diminished ovarian reserve aged between 20-48 years were administered by gonadotropin (Cinnal f, 75 IU, CinnaGen Co.) with the dose of 75IU, 1 ampule in each ovary between day 10-14 menstrual cycles PLUS PRP; 17 ml of peripheral venous blood was drawn in the syringe that contained 3 ml of Acid Citrate A Anticoagulant solution (ACD-A) and centrifuged immediately at 1600 g for 10 min. The blood was divided into three layers: red blood cells at the bottom, cellular plasma in the supernatant and a buffy coat layer between them. The plasma layer and buffy coat were collected to another tube and centrifuged again at 3500 g for 5 min to obtain 3 ml PRP

Category

Treatment - Drugs

3**Description**

Intervention group: Third intervention group: 15 infertile women with diminished ovarian reserve aged between 20-48 years were administered PRP alone; 17 ml of peripheral venous blood was drawn in the syringe that contained 3 ml of Acid Citrate A Anticoagulant solution (ACD-A) and centrifuged immediately at 1600 g for 10 min. The blood was divided into three layers: red blood cells at the bottom, cellular plasma in the supernatant and a buffy coat layer between them. The plasma layer and buffy coat were collected to another tube and centrifuged again at 3500 g for 5 min to obtain 3 ml PRP

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Yazd Reproductive Sciences Institute

Full name of responsible person

Abbas Aflatoonian

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Deputy of Research and Development, Shahid Sadoughi University of Medical Sciences, Yazd, Iran.

Full name of responsible person

Masoud Mirzaei

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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

Deputy of Research and Development, Shahid Sadoughi University of Medical Sciences, Yazd, Iran.

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

Yazd University of Medical Sciences

Full name of responsible person

Abbas Aflatoonian

Position

Professor, Gynecologist, Infertility Fellowship (Head of Institute)

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

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Full name of responsible person

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Position

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Latest degree

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Person responsible for scientific inquiries

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Full name of responsible person

Abbas Aflatoonian

Position

Professor, Gynecologist, Infertility Fellowship (Head of Institute)

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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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

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available