Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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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

City
Yazd

Province
Yazd

Postal code
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 scientific inquiries

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Full name of responsible person
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Position
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Latest degree
Specialist

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Person responsible for updating data

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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