

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

The effect of intraovarian injection of Calcium Gluconate-activated platelet-rich plasma (PRP) on infertile women with diminished ovarian reserve: A before after clinical trial

Protocol summary

Study aim

Detect of effectiveness of intraovarian injection of Calcium Gluconate-activated platelet-rich plasma on infertile women with diminished ovarian reserve

Design

Before and after Clinical trial, without control group, not blind, not randomized

Settings and conduct

Ten infertile women with at least one failed invitro fertilization and diminished ovarian reserve or premature ovarian failure who attending in infertility department in Imam khomainsi Hospital, Mazandaran University of Medical Sciences, Sari, Iran, will be evaluated before and after intraovarian injection of platelet. Patients and physician are aware of intervention and patients' consent to enter the study is obtained

Participants/Inclusion and exclusion criteria

Women aged 20-45 year diminished ovarian reserve
Body mass index lower than 30 Kilogram per square meter
At least one prior failed in vitro fertilization
Premature ovarian failure

Intervention groups

Intrauterine infusion of 0.5 CC of autologous platelet-rich plasma (has 4-6 times platelet concentration rather than peripheral blood by IUI catheter (Takvin company, Iran) on oocyte pick up day.

Main outcome variables

Change in Anti mulerian hormone level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160815029374N7**

Registration date: **2019-06-20, 1398/03/30**

Registration timing: **registered_while_recruiting**

Last update: **2019-06-20, 1398/03/30**

Update count: **0**

Registration date

2019-06-20, 1398/03/30

Registrant information

Name

Marzieh Zamaniyan

Name of organization / entity

Mazandaran University of Medical Sciences, Sari, Iran.

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-29, 1397/11/09

Expected recruitment end date

2019-06-21, 1398/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intraovarian injection of Calcium Gluconate-activated platelet-rich plasma (PRP) on infertile women with diminished ovarian reserve: A before after clinical trial

Public title

Platelet-rich plasma effect in infertility

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diminished ovarian reserve At least one prior failed in vitro fertilization Body mass index lower than 30 Kilogram per square meter Premature ovarian failure

Exclusion criteria:

Hematologic disorders (blood cancer, thrombocytopenia) Immunologic disorders (anti-phospholipid syndrome, thrombophilia) Hormonal disorders (diabetes, thyroid, hyperprolactinemia) Chromosomal anomalies and genetics (hereditary or congenital) Renal failure

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

N/A

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 Mazandaran University of Medical Sciences

Street address

No. 5, third floor, Cancer ward, Imam Khomeini Hospital, Amir Mazandarani Ave, Diabetes Research Center.

City

Sari

Province

Mazandaran

Postal code

3313148166

Approval date

2019-01-28, 1397/11/08

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1398.007

Health conditions studied

1

Description of health condition studied

Diseases of the genitourinary system

ICD-10 code

N97; N98

ICD-10 code description

Female infertility; Complications associated with artificial fertilization

Primary outcomes

1

Description

Change in Anti mulerian hormone level

Timepoint

Two weeks after oocyte pick up compared with two week before injection of of Calcium Gluconate-activated platelet-rich plasma (the day of pick up oocyte)

Method of measurement

Assaying this factor in blood serum is done by laboratory methods and the corresponding kit

2

Description

Changes in the level of follicular stimulating hormone

Timepoint

Two weeks after oocyte pick up compared with two week before injection of of Calcium Gluconate-activated platelet-rich plasma (the day of pick up oocyte)

Method of measurement

Assaying this factor in blood serum is done by laboratory methods and the corresponding kit

3

Description

Change in estradiol level

Timepoint

Two weeks after oocyte pick up compared with two week before injection of of Calcium Gluconate-activated platelet-rich plasma (the day of pick up oocyte)

Method of measurement

Assaying this factor in blood serum is done by laboratory methods and the corresponding kit

Secondary outcomes

1

Description

Change in Antral fulicular counts

Timepoint

The third day of menstruation and before B-HCG injection

Method of measurement

by ultrasound and folliculography

2

Description

Change in oocyte numbers

Timepoint

Two months after Calcium Gluconate- activated platelet-rich plasma injection comparison with the day of Oocyte pick up

Method of measurement

evaluation by microscope and ultrasound

3

Description

Pregnancy rate

Timepoint

Three months after Calcium Gluconate - activated platelet-rich plasma injection then survey chemical and clinical pregnancy

Method of measurement

Positive beta hCG rate and clinical pregnancy rates

4

Description

Change in embryos numbers

Timepoint

Two months after intraovarian injection of platelet

Method of measurement

by counting frozen embryo in embryo bank

Intervention groups

1

Description

Intervention group: Intrauterine infusion of 0.5 CC of autologous Calcium Gluconate- activated platelet-rich plasma (has 4-6 times platelet concentration rather than peripheral blood by IUI catheter(Takvin company, Iran) on day of oocyte pick up.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomai Hospital

Full name of responsible person

Marzieh Zamaniyan

Street address

No. 1, Ground floor, Infertility ward, Imam Khomeini Hospital, Amir Mazandarani Ave,

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marziehzamaniyan@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Reza Alizadeh Navaei

Street address

N0.2, Third floor, Department of Research and Technology, Teachers' Square

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4815733971

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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

Sari 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

Mazandaran University of Medical Sciences

Full name of responsible person

Marzieh Zamaniyan

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity

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research expert
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

No - There is not 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