

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

effects of intra-ovarian injection of autologous platelet rich plasma to ovarian reserve in poor responders

Protocol summary

Study aim

evaluation of the effects of intra-ovarian injection of autologous platelet rich plasma (PRP) to ovarian reserve in poor responders

Design

This is a before and after trial that will be performed on 22 infertile women who have laboratory and ultrasound criteria predicting a poor response to ovarian stimulation. Participants will be stimulated by an antagonist protocol, after oocyte pick up 2 cc of PRP, will be injected into the cortex of each ovaries. Two months later, they will undergo another ovarian stimulation cycle with the same protocol. The number of antral follicular count, AMH, day 2-3 FSH, LH, FSH/LH, the trigger day estradiol level, the number of oocytes obtained will be compared between the two cycles.

Settings and conduct

The present study is a before and after clinical trial. After confirmation of the ethics committee, sampling will be done in the easy and accessible manner, so that the researcher in the infertility clinic of Alzahra hospital after introducing herself, explains the steps of conducting research and obtains informed, written and signed consent from interested patients.

Participants/Inclusion and exclusion criteria

inclusion criteria: AMH less than 1.1; number of antral follicles less than 5-7; history of cycle cancellation due to insufficient follicular growth; history of cycle cancellation due to less than 3 oocytes obtained; willingness to cooperate; exclusion criteria: IGA deficiency; genital or non-genital cancers; treatment with anticoagulants; ovarian failure due to chromosomal abnormality; severe pelvic adhesion; non-acceptance or cooperation of the patient

Intervention groups

On the day of ovulation, after the puncture, two cc of PRP is injected into each ovary in the same session.

Main outcome variables

Number of oocytes obtained; day 2-3 FSH and LH ; AMH;

serum estradiol levels on the triggering day

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101227005485N9**

Registration date: **2021-01-22, 1399/11/03**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-22, 1399/11/03**

Update count: **0**

Registration date

2021-01-22, 1399/11/03

Registrant information

Name

Nazli Navali

Name of organization / entity

Tabriz University of Medical Sciences, Faculty of Medicine

Country

Iran (Islamic Republic of)

Phone

+98 41 1330 2879

Email address

navalin@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-18, 1399/01/30

Expected recruitment end date

2021-02-18, 1399/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
effects of intra-ovarian injection of autologous platelet rich plasma to ovarian reserve in poor responders

Public title
effects of intra-ovarian injection of autologous platelet rich plasma

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Antimullerian hormone (AMH) less than 1.1 number of antral follicles less than 5-7 history of cycle cancellation due to insufficient follicular growth history of cycle cancellation due to less than 3 oocytes obtained willingness to cooperate Ages between 30 and 43 years
Exclusion criteria:
Immunoglobulin A deficiency genital or non-genital cancers treatment with anticoagulants ovarian failure due to chromosomal abnormality severe pelvic adhesion non-acceptance or cooperation of the patient

Age
From **30 years** old to **43 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **22**
More than 1 sample in each individual
Number of samples in each individual: **2**
Before and after injection of platelet-rich plasma

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 Tabriz University of Medical

Street address

Research Deputy of Tabriz University of Medical Sciences, University of Tabriz, Golgasht street

City

Tabriz

Province

East Azarbaijan

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2020-11-09, 1399/08/19

Ethics committee reference number

IR.TBZMED.REC.1399.794

Health conditions studied

1

Description of health condition studied

diminished ovarian reserve

ICD-10 code

N97.0

ICD-10 code description

infertility due to diminished ovarian reserve

Primary outcomes

1

Description

Number of oocytes obtained

Timepoint

Immediately after ovarian puncture before and 2 months after injection of platelet-rich plasma (PRP)

Method of measurement

Under a microscope by an embryologist

2

Description

Follicular Stimulating Hormone (FSH) and Luteinizing Hormone (LH) day two or three of menstruation

Timepoint

Cycle before and 2 months after injection of platelet-rich plasma

Method of measurement

electrochemiluminescence

3

Description

antimullerian hormone

Timepoint

Cycle before and 2 months after injection of platelet-rich plasma

Method of measurement

electrochemiluminescence

4

Description

Comparison of serum estradiol levels on the day of ovulation triggering

Timepoint

Cycle before and 2 months after injection of platelet-rich plasma

Method of measurement

electrochemiluminescence

Secondary outcomes

1

Description

Number of 4 to 8 cells embryos

Timepoint

2 to 3 days

Method of measurement

With a microscope by an embryologist

Intervention groups

1

Description

Intervention group: Immediately after second ovarian puncture, intra-ovarian injection of 2 millilitre of platelet-rich plasma into each ovary will be done. Platelet-rich plasma is taken from the individual's own peripheral blood and centrifuged twice, using standard Ryagen kits approved by the US Food and Drug Administration.

Category

Treatment - Surgery

2

Description

Control group: they are the same participants before any intervention is done, ie intra-ovarian injection will not be performed after the first ovarian puncture.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital Infertility Ward

Full name of responsible person

Dr. Navali Nazli

Street address

South Artesh Street

City

Tabriz

Province

East Azarbaijan

Postal code

5138665793

Phone

+98 41 3554 1221

Email

navalin@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Laya Farzadi

Street address

South Artesh Street

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navalin@tbzmed.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Nazli Navali

Position

infertility fellowship/associate professor

Latest degree

Subspecialist

Other areas of specialty/work

infertility fellowship/associate professor

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Nazli Navali

Position

associate professor/infertility fellowship

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

Contact

Name of organization / entity

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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

It may not be used properly.

Study Protocol

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

Statistical Analysis Plan

Not applicable

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