Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 platelate 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 begone 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 Medecine

Country
Iran (Islamic Republic of)

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+98 41 1330 2879

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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

antimulerian 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 participents 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
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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

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Full name of responsible person

Nazli Navali

Position

associate professor/infertility fellowship

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Gynecology and Obstetrics

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Person responsible for updating data

Contact

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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