Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effect of intraovarian platelet rich plasma injection on ovarian folliculogenesis and intracytoplasmic sperm injection outcome in poor responders- Quasi-Experimental Study

Protocol summary

Study aim

The purpose of this study is to investigate the effectiveness of intraovarian platelet-rich plasma injection on ovarian folliculogenesis and the results of intracytoplasmic sperm injection.

Design

In Quasi-Experimental study with a before-and-after design, 20 patients with poor ovarian response will be enrolled in a single group in the period of 2024-2025 at Mehr medical Institute. Blinding and randomization are not valid in this study.

Settings and conduct

The present study will be conducted at Mehr Medical Institute. Pituitary suppression will be done using the agonist method. Ovarian follicles will be obtained using vaginal ultrasound. Platelet rich plasma will be prepared according to the instructions. After oocyte retrival, 1.5 ml of PRP will be injected into each ovary using a G17, 35 cm single lumen needle and guided by ultrasound. In the third menstrual cycle after PRP treatment, all participants will receive the GnRH agonist protocol and undergo a second cycle of ICSI.

Participants/Inclusion and exclusion criteria

Patients with poor ovarian reserve Inclusion criteria: Age less than 40 years- The number of antral follicles less than 5- Anti-Müllerian hormone level less than 0.3 nano-grams/milliliter- Exclusion criteria: Women with autoimmune disorders- Anemia- Thrombophilic disorders- Current cancer or medical history of cancer- Severe male infertility- Endometriosis

Intervention groups

After oocyte retrieval, 1.5 ml of platelet-rich plasma will be injected into each ovary under ultrasound guidance.

Main outcome variables

The total number of oocytes retrieved- The total number of metaphase II oocytes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180528039878N5**
Registration date: **2024-03-04, 1402/12/14**
Registration timing: **prospective**

Last update: **2024-03-04, 1402/12/14**
Update count: **0**

Registration date

2024-03-04, 1402/12/14

Registrant information

Name

Marzieh Mehrafza

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3376 4270

Email address

dr.Mehrafza@mehrinstitute.org

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-05-21, 1403/03/01

Expected recruitment end date

2025-08-23, 1404/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the effect of intraovarian platelet rich plasma injection on ovarian folliculogenesis and intracytoplasmic sperm injection outcome in poor responders- Quasi-Experimental Study

Public title
PRP effect on ovary
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age less than 40 years The number of antral follicles is less than 5 Anti-Müllerian hormone level less than 0.3 nano-grams/milliliter
Exclusion criteria:
Women with autoimmune disorders Anemia Thrombophilic disorders Current cancer or medical history of cancer Severe male infertility Endometriosis
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **20**
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 Guilan University of Medical Sciences
Street address
Mehr Medical Institute, Irshad St, Shahid Ansari BLvd, Rasht
City
Rasht
Province
Guilan
Postal code
417861311
Approval date
2024-02-14, 1402/11/25
Ethics committee reference number
IR.GUMS.REC.1402.584

Health conditions studied

1

Description of health condition studied
Primary ovarian failure
ICD-10 code
E28.3
ICD-10 code description
Primary ovarian failure

Primary outcomes

1

Description
The total number of oocytes retrieved
Timepoint
The day of ovarian puncture before platelet rich plasma injection, The day of ovarian puncture after platelet rich plasma injection
Method of measurement
According to the count

2

Description
The total number of metaphase II oocytes
Timepoint
The day of ovarian puncture before platelet rich plasma injection, The day of ovarian puncture after platelet rich plasma injection
Method of measurement
According to the count

Secondary outcomes

1

Description
Basal level of Anti-Müllerian Hormone
Timepoint
Serum level on the third day of the menstrual cycle before platelet-rich plasma injection, Serum level on the third day of the menstrual cycle after platelet-rich plasma injection
Method of measurement
Using the test kit

2

Description
Number of embryos
Timepoint
In the cycle before platelet-rich plasma injection, In the cycle after platelet-rich plasma injection
Method of measurement

According to the count

Intervention groups

1

Description
Intervention group: Intraovarian injection of platelet-rich plasma - 8.5 ml of peripheral venous blood will be drawn into a 10 ml syringe containing 1.5 ml of anticoagulant solution. According to the instructions of the kit (Royagen, Iran), 3 ml of lympho-plasma platelet-rich with a platelet concentration 4 to 5 times higher than the base blood and 2000 lymphocytes per microliter will be prepared.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Mehr Medical Institute
Full name of responsible person
Marzieh Mehrafza
Street address
Mehr Medical Institute, Irshad St., Shahid Ansari Blvd
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http://www.mehrinstitute.org/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mehr Medical Institute
Full name of responsible person
Marzieh Mehrafza
Street address
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http://www.mehrinstitute.org/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mehr Medical Institute
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Mehr Medical Institute
Full name of responsible person
Marzieh Mehrafza
Position
Non-faculty subspesialist M.D
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for scientific inquiries

Contact
Name of organization / entity

Mehr Medical Institute

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Person responsible for updating data

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

Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
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