Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jul 2026

Investigating the effectiveness of intraovarian injection of platelet rich plasma on ovarian reserve in infertile women due to decreased ovarian reserve

Protocol summary

Study aim
A Pre/Post study of intra-ovarian PRP injection efficacy in infertile women due to diminished ovarian response in Shohadaye-Tajrish and Taleqani general hospitals through 2022-2023

Design
In all women included in the study, on the first to third day of menstruation under ultrasound (if there is no follicle above 10 mm and the thickness of the endometrium is below 5 mm and ovulation) and treatment with Pergoveris injectable gonadotropin twice a day, and when the growing follicle reaches 12-14 mm in size, GnRH antagonist (0.25 mg/day cetrotide) will be started subcutaneously. This injection will continue until the day of (ovitrelle (recombinant HCG (250 micrograms)) administration. When the dominant follicle reaches 18 mm, ovulation is induced using (ovitrelle (recombinant HCG (250 micrograms)) and transvaginal oocyte retrieval during 34 to 36 hours after the injection (ovitrelle (recombinant HCG (250 micrograms)) will be performed with an ultrasound guide. On the day of ovulation, after ovarian puncture, 3 cc of PRP injection will be performed. If the IVF cycle fails, on the third Menstrual cycle After checking the serum level of FSH, AMH and the presence of at least one AFC in the ultrasound, the patients are again included in the ovulation stimulation cycle.

Settings and conduct
Shohada Tajrish Hospital

Participants/Inclusion and exclusion criteria
Inclusion criteria Infertile women under the age of 42 with diminished ovarian reserve such as AMH<1ng/ml or AFC<5 and infertile women with poor ovarian response: with a history of recovering less than 5 eggs in IVF Non-entry criteria Infertility due to inflammation, endometriosis and PID, hyperandrogenism and PCO, anatomical disorder, male factor, platelet deficiency and bleeding disorders.

Intervention groups
Infertile women due to reduced ovarian reserve

Main outcome variables
ovarian reserve

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160722029027N14**
Registration date: **2024-01-31, 1402/11/11**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-31, 1402/11/11**
Update count: **0**

Registration date
2024-01-31, 1402/11/11

Registrant information

Name
Leila Nazari

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-01, 1402/10/11

Expected recruitment end date

2024-02-19, 1402/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of intraovarian injection of platelet rich plasma on ovarian reserve in infertile women due to decreased ovarian reserve

Public title

Investigating the effectiveness of intraovarian injection of platelet rich plasma on ovarian reserve in infertile women due to decreased ovarian reserve

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women with infertility under 42 years old with diminished ovarian reserve as AMH<1ng/ml or AFC<5 Infertile women with poor ovarian response: with a history of retrieving less than 5 eggs in IVF

Exclusion criteria:

Infertility due to inflammation Endometriosis and PID Hyperandrogenism and PCO Anatomical disorder Anatomical disorder Platelet defects bleeding disorders

Age

From **18 years** old to **42 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **15**

Randomization (investigator's opinion)

N/A

Randomization description

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

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Ethics committee of Shahid Beheshti University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2023-12-31, 1402/10/10

Ethics committee reference number

IR.SBMU.MSP.REC.1402.516

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Reduced ovarian reserve: AMH serum level<1ng/ml or AFC<5 in women under 42 years of age

Timepoint

2 months

Method of measurement

In all women included in the study, on the first to third day of menstruation under ultrasound (if there is no follicle above 10 mm and the thickness of the endometrium is below 5 mm and ovulation) and treatment with Pergoveris injectable gonadotropin twice a day, and when the growing follicle reaches 12-14 mm in size, GnRH antagonist (0.25 mg/day cetrotide) will be started subcutaneously. This injection will continue until the day of (ovitrelle (recombinant HCG) (250 micrograms) administration. When the dominant follicle reaches 18 mm, ovulation is induced using (ovitrelle (recombinant HCG (250 micrograms)) and transvaginal oocyte retrieval during 34 to 36 hours after the injection (ovitrelle (recombinant HCG (250 micrograms)) will be performed with ultrasound guidance. On the day of ovulation, after ovarian puncture, 3 cc of PRP injection will be performed. If the IVF cycle fails, on the third Menstrual cycle After checking the serum level of FSH, AMH and the presence of at least one AFC in the ultrasound, the patients are again included in the ovulation stimulation cycle.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In all women included in the study and after collecting background information such as demographic characteristics and records related to previous pregnancy, on the first to third day of menstruation under ultrasound (if there is no follicle above 10 mm and the thickness of the endometrium is below 5 mm and ovulation) and treatment with Pergoveris injectable gonadotropin twice a day, and when the growing follicle reaches 12-14 mm in size, GnRH antagonist (0.25 mg/day cetrotide) will be started subcutaneously. This injection will continue until the day of (ovitrelle (recombinant HCG) (250 micrograms) administration. When the dominant follicle reaches 18 mm, ovulation is induced using (ovitrelle (recombinant HCG (250 micrograms)) and transvaginal oocyte retrieval during 34 to 36 hours after the injection (ovitrelle (recombinant HCG (250 micrograms)) will be performed with ultrasound guidance. On the day of ovulation, after ovarian puncture, 3 cc of PRP injection will be performed. If the IVF cycle fails, on the third Menstrual cycle After checking the serum level of FSH, AMH and the presence of at least one AFC in the ultrasound, the patients are again included in the ovulation stimulation cycle.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
بیمارستان شهدای تجریش

Full name of responsible person
Leila Nazari

Street address
Tehran-Shohada Tajrish Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Deputy Research and Technology

Street address
Deputy of Research and Technology of Shahid Beheshti University of Medical Science

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sec.bms@acecr.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Leila Nazari

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
6 months after the end of the study
When the data will become available and for how long
6 months after the end of the study
To whom data/document is available
6 months after the end of the study
Under which criteria data/document could be used
6 months after the end of the study
From where data/document is obtainable
6 months after the end of the study - project manager
What processes are involved for a request to access data/document
6 months after the end of the study, she can request from the project manager
Comments