Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of intraovarian administration of platelet rich plasma in patients with poor ovarian response in improving the result of assisted procedures

Protocol summary

Study aim
Determination of the effect of intraovarian administration of platelet-rich plasma in patients with poor ovarian response following the use of assisted reproductive methods

Design
In a clinical trial study with a control group, with parallel groups, with blinding, randomized, phase 3, on 88 infertile women with reduced ovarian reserve, they are randomly placed in one of the two groups of intraovarian injection of PRP and control. Randomization is done using the Random between function software of the Excel program.

Settings and conduct
This work is done in Bandar Abbas infertility center on 2 groups of infertile women with reduced ovarian reserve.

Participants/Inclusion and exclusion criteria
Inclusion criteria: • Informed consent of the patient • Patients aged 18 to 45 years • Normal sperm test • POR Exclusion criteria: • Unwillingness to continue cooperation • Abnormal sperm test • Patients under 18 years old and over 45 years old

Intervention groups
People are randomly assigned to one of the two groups of PRP intraovarian injection and the control group (without PRP injection).

Main outcome variables
The number of retrieved oocytes, the number of retrieved metaphase two oocytes, the serum level of AMH hormone two months after the intervention, the clinical pregnancy rate, the ongoing pregnancy rate, the live birth rate, the number of canceled IVF cycles.

General information

Reason for update
Acronym

IRCT registration information
IRCT registration number: **IRCT20200905048630N5**
Registration date: **2023-09-22, 1402/06/31**
Registration timing: **prospective**

Last update: **2023-09-22, 1402/06/31**
Update count: **0**

Registration date
2023-09-22, 1402/06/31

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-10-23, 1402/08/01
Expected recruitment end date
2024-03-18, 1402/12/28
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of intraovarian administration of platelet rich plasma in patients with poor ovarian

response in improving the result of assisted procedures

Public title
Investigating the effect of intraovarian administration of platelet rich plasma in patients with poor ovarian response in improving the result of assisted procedures

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Informed consent of the patient (completion of the patient consent form by the patient or the patient's companion) Patients aged 18 to 45 years. Patients who have no history of ovarian surgery or ovarian endometrioma. Normal sperm analysis • POR (age over 40 years and/or a history of poor response to high-dose stimulation with less than three oocytes and/or adverse ovarian reserve tests including AMH < 1.1 ng/nl; AFC < 7) Patients without endocrine disorders such as hyperprolactinemia, PCOS, etc. Non-smoking patients Patients who do not have cardiovascular disorders.

Exclusion criteria:
Adhesion or severe damage to the pelvis or ovaries Immunological diseases Hematological diseases Platelets less than one hundred and fifty thousand per cubic millimeter Systemic use of corticosteroids within two weeks before the procedure Taking anticoagulants

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
3

Groups that have been masked

- Data analyser

Sample size
Target sample size: **88**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible patients (including 88 patients) are randomly assigned by a statistical expert using simple randomization method. In this method, the Random between function of the Excel program is used to generate a random number between the number 1 and 2. This work was repeated 88 times and thus a random sequence is obtained.

Blinding (investigator's opinion)
Single blinded

Blinding description
The data analyst will not know about the allocation of groups and the type of intervention performed, and the data will be provided to the analyst in the form of two groups A and B (without mentioning the names of the control group and the intervention group).

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic committee of Hormozgan University of medical sciences

Street address
Deputy of research and technology, campus of Hormozgan University of Medical Sciences, Imam Hossein boulevard, Bandar Abas, Iran

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Bandar Abbas

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Hormozgan

Postal code
7919693116

Approval date
2023-09-17, 1402/06/26

Ethics committee reference number
IR.HUMS.REC.1402.279

Health conditions studied

1

Description of health condition studied
Reducedovarian reserve.

ICD-10 code
E28.3

ICD-10 code description
Primary ovarian failure

Primary outcomes

1

Description
The number of retrieved oocytes

Timepoint
Two months after prp injection

Method of measurement
Count the number

2

Description
The number of MII oocyte obtained

Timepoint
Two months after prp injection

Method of measurement
Count the number

3

Description
Increase in AMH

Timepoint
The day of the prp injection, and then two months after the prp injection
Method of measurement
laboratory test

Secondary outcomes

1

Description
IVF cycle cancellation rate
Timepoint
Two months after PRP injection
Method of measurement
Count the number

2

Description
Clinical pregnancy rate
Timepoint
6 weeks after embryo transfer
Method of measurement
Vaginal ultrasound

3

Description
live birth rate
Timepoint
9 months after embryo transfer
Method of measurement
Count the number

4

Description
ongoing pregnancy rate
Timepoint
20 weeks after embryo transfer
Method of measurement
Ultrasound

Intervention groups

1

Description
Intervention group: 29 infertile women with reduced ovarian reserve between 18 and 45 years of age with the administration of platelet-rich plasma alone, which is prepared and injected as follows: about 8.5 cc of the patient's blood sample in two tubes containing total anticoagulant and centrifuged the sample for 10 minutes at 1600 rpm, after the end of the first round of centrifugation, transfer the upper turbid plasma to another tube and centrifuge again for 6 minutes at 3500 rpm we show At the end of the second cycle, a white deposit should be seen at the bottom of the tube. Discard the supernatant solution containing platelet-free plasma and gently stir the remaining amount and inject one and a half cc of PRP with a concentration of approximately 4-5 times that of platelets into the ovary with the help of a follicular aspiration needle under ultrasound guidance
Category
Treatment - Drugs

2

Description
Control group: 59 infertile women with reduced ovarian reserve between 18 and 45 years without administration of platelet-rich plasma
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Infertility Center of Hormozgan University of Medical Sciences
Full name of responsible person
Dr Maryam Azizi Kutenaee
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Sponsors / Funding sources

1

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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
Bandare-abbas 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
Bandare-abbas University of Medical Sciences
Full name of responsible person
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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
No - There is not 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
Title and more details about the data/document
The data will be presented in the article after analysis
When the data will become available and for how long
2025
To whom data/document is available
Academic researchers and gynecologists and obstetricians

Under which criteria data/document could be used

Clinical use in patients with reduced ovarian reserve

From where data/document is obtainable

corresponding author of the article

What processes are involved for a request to access data/document

Email to the corresponding author

Comments