Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the therapeutic effect of PRP (Platelet-Rich Plasma) in improving ovarian function in patients with infertility

Protocol summary

Study aim
Determining the therapeutic effect of platelet rich plasma on ovarian function in women with infertility due to poor ovarian function

Design
The clinical trial included an intervention group including 20 patients

Settings and conduct
The statistical population of the study will be 20 infertile women referred to Roish Birjand clinic with poor response to ovarian stimulation and candidates for IVF. First, the measurement of AMH, FSH, LH and AFC number of patients before the intervention, then rich plasma injection of platelets in the follicular phase and in the early periods of the menstrual cycle, under sterile conditions and under the guidance of transvaginal ultrasound, will be performed in each ovary by a gynecologist. Finally, hormonal tests of AMH, FSH, LH and ultrasound will be done by a gynecologist to determine the number of AFC in the first menstrual cycle after treatment to determine the effect.

Participants/Inclusion and exclusion criteria
Entry requirements: Age range from 25 to 45 years The amount of FSH hormone is higher than 12 The amount of AMH hormone is lower than 1 Poor response to ovulation stimulating drugs in previous cycles Donor egg candidate Non-entry conditions: The presence of any ovarian cyst confirmed by a gynecologist People with polycystic ovary confirmed by a gynecologist People with underlying medical diseases (hypertension and diabetes)

Intervention groups
Women with poor response to ovarian stimulation First, measuring the hormones AMH, FSH, LH, and the AFC number of the patients before the intervention, then prp injection in the follicular phase, under the guidance of transvaginal ultrasound in each ovary, finally AMH hormone tests. FSH, LH and determine the number of AFC in the first menstrual cycle after treatment to determine the effect.

Main outcome variables
FSH, LH, AMH hormone leveles, AFC numberes

General information

Reason for update

Acronym
prp

IRCT registration information
IRCT registration number: **IRCT20181216042006N2**
Registration date: **2023-04-11, 1402/01/22**
Registration timing: **registered_while_recruiting**

Last update: **2023-04-11, 1402/01/22**
Update count: **0**

Registration date
2023-04-11, 1402/01/22

Registrant information

Name
Mohammad Fereidouni

Name of organization / entity

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Iran (Islamic Republic of)

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+98 56 3243 3004

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-02-20, 1401/12/01

Expected recruitment end date
2025-02-19, 1403/12/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the therapeutic effect of PRP (Platelet-Rich Plasma) in improving ovarian function in patients with infertility

Public title

Investigating the therapeutic effect of PRP (Platelet-Rich Plasma) in ovarian function

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age range from 25 to 45 years The amount of FSH hormone is higher than 12 The amount of AMH hormone is lower than 1 Poor response to ovulation stimulating drugs in previous cycles Donor egg candidate

Exclusion criteria:

The presence of any ovarian cyst confirmed by a gynecologist People with polycystic ovary confirmed by a gynecologist People with underlying medical diseases (hypertension and diabetes)

Age

From **25 years** old to **45 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Not randomized

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 Committeeof Birjand University of Medical Sciences

Street address

Birjand University of Medical Sciences, 21/1 Ghafari corner, Ayatollah Ghafari St, Birjand city, South Khorasan province, Iran

City

BIRJAND

Province

South Khorasan

Postal code

9717853076

Approval date

2023-02-20, 1401/12/01

Ethics committee reference number

ir. bums. REC.1401. 409

Health conditions studied

1

Description of health condition studied

Women with poor response to ovarian stimulation

ICD-10 code

N97.0

ICD-10 code description

Female infertility associated with anovulation

Primary outcomes

1

Description

FSH hormone level

Timepoint

A few days before the injection and the first menstrual cycle after the injection

Method of measurement

Measurement in the laboratory

2

Description

AMH hormone level

Timepoint

A few days before the injection and the first menstrual cycle after the injection

Method of measurement

Measurement in the laboratory

3

Description

LH hormone level

Timepoint

A few days before the injection and the first menstrual cycle after the injection

Method of measurement

Measurement in the laboratory

4

Description

AFC number

Timepoint

A few days before the injection and the first menstrual cycle after the injection

Method of measurement
sonography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: (Women with poor response to ovarian stimulation) The statistical population of the study will be 20 infertile women referred to Roish Birjand clinic with poor response to ovarian stimulation and IVF candidates. The results of the tests related to AMH, FSH, LH and the number of AFC of the patients will be recorded by reviewing the patients' files before the intervention. The next step is the sampling of the PRP preparation. From all participants, 20 cc of blood with citrate anticoagulant will be taken. It will be taken. Using a centrifuge at a specified speed, the plasma will be separated and transferred to sterile tubes. In the next step, a high-speed centrifuge is performed according to the instructions of the kit to separate the platelet-rich plasma.In the follicular phase and in the early periods of the menstrual cycle, PRP injection will be performed under sterile conditions and under the guidance of transvaginal ultrasound in each ovary under general anesthesia by an anesthesiologist in the operating room of Roish Clinic in a stromal manner by a gynecologist. After regaining consciousness, she will be discharged. Finally, hormonal tests of AMH, FSH, LH and sonography will be performed by a gynecologist to determine the number of AFC in the first menstrual cycle after treatment to determine the effect.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Roiesh Infertility Clinic
Full name of responsible person
vajihe hazari
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Roish Infertility and Infertility Center, Center for Special Diseases, Beheshti Third Corner, Shahid Beheshti St., Birjand, South Khorasan Province, Iran
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2

Recruitment center
Name of recruitment center
Comprehensive research laboratory of Birjand University of Medical Sciences
Full name of responsible person
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Comprehensive Research Laboratory, Cellular and Molecular Research Center, Faculty of Medicine, Birjand University of Medical Sciences,21/1 Ghafari Corner, Ayatollah Ghafari Street, Birjand City, South Khorasan Province, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Research and Technology Vice-Chancellor, Birjand University of Medical Sciences,21/1 Ghafari Corner, Ayatollah Ghafari Street, Birjand City, South Khorasan Province, Iran
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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
Birjand 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
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assistant professor
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Person responsible for updating data

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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
Due to the privacy of patients
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
The study protocol, statistical analysis map, clinical study report will be made available after the article is published.
When the data will become available and for how long
after the article is published
To whom data/document is available
Researchers working in academic institutions
Under which criteria data/document could be used

Use in retrospective studies

From where data/document is obtainable

Birjand Cell and Molecular Research Center

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

Request from the Research Vice-Chancellor, to be submitted to the Research Council, and if the request is accepted, the request will be referred to a research expert and receive data.

Comments