

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 56 3243 3004

##### Email address

dr.m.fereidouni@gmail.com

##### 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 Committee of 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

dr.vhazari@gmail.com

**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

**Street address**

Roish Infertility and Infertility Center, Center for Special Diseases, Beheshti Third Corner, Shahid Beheshti St., Birjand, South Khorasan Province, Iran

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**Postal code**

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**Phone**

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**Email****2****Recruitment center****Name of recruitment center**

Comprehensive research laboratory of Birjand University of Medical Sciences

**Full name of responsible person**

Mohammad fereidouni

**Street address**

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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dr.fereidouni@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Masoud yousefi

**Street address**

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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masoud.yousefi@bums.ac

**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**

Birjand University of Medical Sciences

**Full name of responsible person**

Atena mansouri

**Position**

assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Nanotechnology

**Street address**

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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mansouri\_atena@bums.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

mohammad fereidouni

**Position**

Full professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Immunology

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**Person responsible for updating data****Contact****Name of organization / entity**

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**Full name of responsible person**

Atena mansouri

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Nanotechnology

**Street address**

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**Email**

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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**