

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### The effect of autologous PRP on ovarian reserve in patients undergoing laparoscopic endometriosis surgery

#### Protocol summary

##### Study aim

The effect of platelet-rich plasma (PRP) on ovarian reserve in patients undergoing laparoscopic endometriosis surgery

##### Design

A clinical trial with two intervention and control groups performed on 30 patients undergoing laparoscopic endometriosis.

##### Settings and conduct

This study will be performed in Hazrat Rasool Akram Hospital. After providing the necessary explanations about this plan, written consent will be obtained from the patients. In the intervention group, venous blood is taken from patients and platelet-rich plasma is isolated and injected to ovary with cyst under laparoscopic surgery. No blinding has been done

##### Participants/Inclusion and exclusion criteria

Inclusion criteria included endometriosis women candidates for laparoscopic surgery with a diameter of 4 to 10 cm, which was confirmed by ultrasound, body mass index (BMI = mass (kg) / height<sup>2</sup> (m)) between 18.5 to 30, have not received hormonal drugs, especially GnRH agonists in the last 3 months and the amount of AMH is less than 1/1 ng. Women with a body mass index (BMI) of 30 or less than 5.18, people with autoimmune disorders and malignancies, sexually transmitted diseases, infectious diseases, infertility following tubal obstruction, and patients with endocrine disorders such as thyroid dysfunction And patients taking anticoagulants are excluded from the study.

##### Intervention groups

Both intervention and control groups undergo laparoscopic endometriosis surgery. In the intervention group, platelet-rich plasma is injected into the ovarian tissue during laparoscopy. Serum AMH levels are measured in both groups 6 months after surgery.

##### Main outcome variables

AMH levels and number of antral follicles (AFC)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191123045476N3**

Registration date: **2021-12-01, 1400/09/10**

Registration timing: **prospective**

Last update: **2021-12-01, 1400/09/10**

Update count: **0**

##### Registration date

2021-12-01, 1400/09/10

##### Registrant information

##### Name

Samaneh Rokhgireh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6650 9283

##### Email address

rokhgireh.s@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-12-11, 1400/09/20

##### Expected recruitment end date

2022-05-10, 1401/02/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of autologous PRP on ovarian reserve in patients undergoing laparoscopic endometriosis surgery

**Public title**

The effect of PRP on ovarian reserve

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Endometriosis women are candidates for laparoscopic surgery with a diameter of 4 to 10 cm, which is confirmed by ultrasound BMI between 18.5 and 30 have. Have not received hormonal drugs, especially GnRH agonists, in the last 3 months. AMH should be less than 1/1 ng.

**Exclusion criteria:**

Women with a body mass index (BMI) greater than 30 or less than 18/5 People with autoimmune disorders and malignancies People with sexually transmitted and infectious diseases People with infertility following tubal obstruction and patients with endocrine disorders such as thyroid dysfunction Patients who use anticoagulant drugs

**Age**

From **20 years** old to **35 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, restricted randomization sampling method is used that the study groups have equal sample size. Random allocation rule is one of the limited random sampling methods used in the present study. And patients are equally divided into two groups. On how to randomize, researchers first determine a total sample size, then randomly assign a set of them to group A and the rest to group B. For example, in a study with a sample size of 200 people, 100 balls For intervention group A and 100 balls, for intervention group B, it is placed in a lottery container and then the balls are randomly removed from the container without replacement and the created sequence is recorded. This method is used for two or more group trials.

**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 Iran University of Medical Sciences

**Street address**

Sattar Khan St., Maziar Mansouri St., Rasoul Akram Hospital

**City**

Tehran

**Province**

Tehran

**Postal code**

1445613131

**Approval date**

2021-09-12, 1400/06/21

**Ethics committee reference number**

IR.IUMS.REC.1400.521

**Health conditions studied****1****Description of health condition studied**

Laparoscopy of endometriosis

**ICD-10 code**

N80

**ICD-10 code description**

Endometriosis

**Primary outcomes****1****Description**

AMH hormone level

**Timepoint**

6 months after surgery

**Method of measurement**

Blood test

**2****Description**

Number of Antral Follicles (AFC)

**Timepoint**

6 months after surgery

**Method of measurement**

Sonography

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: the patient is injected with concentrated plasma, which is rich in platelets, according to the study protocol. Before the operation, 20 cc of the patient's blood is taken in a PRP tube (GeoPRP-regenlab kit). The tube is completely shaken and its contents are centrifuged at 3600 rpm for 6 minutes and the surface PRP is collected with a 16-gauge needle. The result is about 4-8 cc of PRP. After laparoscopy cystectomy, 2-4 cc is injected subcortically into the ovary with endometrial cyst.

**Category**

Treatment - Drugs

**2****Description**

Control group: In the control group, endometriosis patients with ovarian cysts undergo only laparoscopic surgery and PRP injection is not performed.

**Category**

Treatment - Surgery

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Rasool Akram Hospital

**Full name of responsible person**

Samaneh Rokhgireh

**Street address**

Starkhan.Mansouri Street. Rasoul Akram Hospital

**City**

Tehran

**Province**

Tehran

**Postal code**

1445613131

**Phone**

+98 21 6435 1000

**Email**

s.rokhgireh@gmail.com

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

Iran University of Medical Sciences

**Full name of responsible person**

Samaneh Rokhgireh

**Street address**

Sattarkhan-Mansoori Street.Rasoul Akram Hospital

**City**

Tehran

**Province**

Tehran

**Postal code**

1445613131

**Phone**

+98 21 6435 1000

**Email**

s.rokhgireh@gmail.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Samaneh Rokhgireh

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Sattar Khan .Mansouri St. Rasoul Akram Hospital

**City**

Tehran

**Province**

Tehran

**Postal code**

1445613131

**Phone**

+98 21 6435 1000

**Email**

s.rokhgireh@gmail.com

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

Iran University of Medical Sciences

**Full name of responsible person**

Samaneh Rokhgireh

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Sattar Khan .Mansouri St. Rasoul Akram Hospital

**City**

Tehran

**Province**

Tehran

**Postal code**

1445613131

**Phone**

+98 21 6435 1000

**Email**

s.rokhgireh@gmail.com

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

Iran University of Medical Sciences

**Full name of responsible person**

Samaneh Rokhgireh

**Position**

professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Sattar Khan .Mansouri St. Rasoul Akram Hospital

**City**

Tehran

**Province**

Tehran

**Postal code**

1445613131

**Phone**

+98 21 6435 1000

**Email**

s.rokhgireh@gmail.com

**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**

Following the publication of the article, confidential information such as patient profile and Hospital, ... deletion and other information Will be made available to researchers

**When the data will become available and for how long**

After publishing the article

**To whom data/document is available**

Medical specialists

**Under which criteria data/document could be used**

Medical professionals can turn to data for research purposes gain access

**From where data/document is obtainable**

Refer to the email of the responsible author

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

Official and academic email to the responsible author

**Comments**