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^2 (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)
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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

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Starkhan.Mansouri Street. Rasoul Akram Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

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

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Person responsible for updating data

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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
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