Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

: Comparison the effect of ovarian PRP with and without vaginal RF on the number of oocyte and embryos in patients with diminished ovarian reserve and candidates for IVF

Protocol summary

Study aim

Comparative study of the effect of ovarian platelet-Rich plasma with and without vaginal Radiofrequency on the number of eggs and embryos in people with reduced ovarian reserve and InVitroFertilization candidates

Design

Phase 3 randomized, parallel-group, controlled clinical trial on 60 patients using G*power software

Settings and conduct

Study population: Patients will be divided into two groups, the intervention group includes people who undergo vaginal RF in addition to ovarian PRP, and the second group will undergo ovarian PRP without vaginal RF. Individuals from the research team who are involved in random assignment and intervention will not be involved in examining the study outcomes (dependent variables). The study location is Nikan Hospital, Tehran.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having decreased ovarian reserve based on the definition of "antral follicle count or AFC less than 5 to 7 follicles and AMH level less than 1.1 ng/ml who referred due to infertility. Normal vaginal endo-cytology without any evidence of malignancy with atypia. Non-entry criteria: receiving hormone replacement in the past six months, having a pacemaker or any metal device in the pelvic area.

Intervention groups

The intervention group consists of patients with diminished ovarian reserve who receive PRP with vaginal radiofrequency intervention. The comparison group consists of patients with diminished ovarian reserve who receive PRP only.

Main outcome variables

1) number of oocytes retrieved and 2) number of fetuses transferred, 3) any unwanted side effects during treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160722029027N15**
Registration date: **2025-08-26, 1404/06/04**
Registration timing: **registered_while_recruiting**

Last update: **2025-08-26, 1404/06/04**
Update count: **0**

Registration date

2025-08-26, 1404/06/04

Registrant information

Name

Leila Nazari

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-08-03, 1404/05/12

Expected recruitment end date

2028-03-20, 1407/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
: Comparison the effect of ovarian PRP with and without vaginal RF on the number of oocyte and embryos in patients with diminished ovarian reserve and candidates for IVF

Public title
Studying the effectiveness of vaginal radiofrequency on ovarian reserve in people with reduced ovarian reserve

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Having diminished ovarian reserve as defined by an antral follicle count or AFC of less than 5 to 7 follicles and an AMH level of less than 1.1 ng/ml who presented for infertility. Normal vaginal endocytology without any evidence of malignancy with atypia. Not receiving hormone replacement therapy for six months, no pacemaker or any metal device in the pelvic area.

Exclusion criteria:
For any reason, the patient is unwilling to participate in the study.

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

Gender
Female

Phase
3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Random assignment of individuals to the intervention and control groups will be done as described using cards placed inside Sequentially Numbered Sealed Opaque Envelopes (SNOSE). These cards will be prepared in the same number as the intervention and control groups (e.g., cards numbered one for the intervention group and numbered two for the control group) and will be placed inside the sealed opaque envelopes. After shuffling the envelopes, each person meeting the inclusion criteria will select an envelope to determine their study group.

Blinding (investigator's opinion)
Single blinded

Blinding description
Individuals from the research team who are involved in the random assignment and intervention (PRP with and without vaginal radioferquency) will not be involved in examining the study outcomes (dependent variables).

Placebo
Not used

Assignment
Parallel

Other design features
The present study is the first to evaluate the effect of ovarian PRP with and without vaginal RF on the number of eggs and embryos in individuals with DOR and candidates for IVF.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shahid Beheshti University of Medical Sciences ethics committee

Street address
Ghadir building,Shohadaye Tajrish hospital,Qods square,Tajrish

City
Tehran

Province
Tehran

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1234567890

Approval date
2025-08-02, 1404/05/11

Ethics committee reference number
IR.SBMU.RETECH.REC.1403.805

Health conditions studied

1

Description of health condition studied
Decreased ovarian reserve

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Number of oocyte

Timepoint
Before and after vaginal RF

Method of measurement
Counting with a microscope

2

Description
Number of embryo

Timepoint
Before and after vaginal RF

Method of measurement
Counting with a microscope

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:The intervention group includes people who undergo vaginal RF in addition to ovarian PRP. First, patients enter an IVF cycle with a fixed protocol, and simultaneously with ovarian puncture and egg extraction, ovarian PRP is performed in such a way that a sample is prepared from the individual's peripheral blood and blood platelets are extracted 4-5 times and injected in an amount of 1.5 cc into each ovary. The number of eggs and embryos obtained in both groups is recorded. Then, in the intervention group, they undergo vaginal RF in 4 sessions over a period of 2 months. In these patients, RF is performed in the form of capacitive electrical transmission, in a monopolar configuration, which has two electrodes, one placed in the vaginal area and the other in the lumbosacral area. Participants are placed in the supine position. The temperature will be set to 45 degrees Celsius, with a frequency of 1 MHz and a power of 80 kilojoules. Once the desired temperature is reached, the interventional researcher holds it in a semicircular motion on the lateral walls of the vagina for 30 minutes. Each patient will undergo RF treatment for 4 sessions at 2-week intervals over 2 months. Both groups will be re-entered into the IVF cycle and the number of oocytes and embryos retrieved will be recorded. Finally, the average number of oocytes and embryos in both groups before and after vaginal RF is compared. After the treatment period, patients will be evaluated for the following outcomes: 1) number of oocytes retrieved and 2) number of embryos retrieved, 3) any unwanted treatment complications during treatment, and 4) patient satisfaction with the treatment protocol on a five-level scale of completely dissatisfied, somewhat dissatisfied, no opinion, somewhat satisfied, and completely satisfied.

Category

Treatment - Devices

2

Description

Control group: In the control group, ovarian PRP is performed without vaginal RF. In this way, patients enter the IVF cycle with a fixed protocol, and simultaneously with ovarian puncture and egg extraction, ovarian PRP is performed in this way that a sample is prepared from the individual's peripheral blood and blood platelets are extracted 4-5 times and injected in an amount of 1.5 cc into each ovary. The number of eggs and embryos obtained is recorded. In this group, the vaginal RF maneuver is also performed every 2 weeks, but in a simulated manner and without turning on the device. Then, both groups are entered into the IVF cycle again, and the number of eggs and embryos obtained is recorded. Finally, the average number of eggs and embryos in both groups before and after vaginal RF is compared with each other. After the treatment period, patients are evaluated for the following outcomes: 1) number of oocytes retrieved, 2) number of embryos obtained, 3) any unwanted treatment complications during treatment, and 4) patient satisfaction level with the treatment protocol on a five-level scale of completely dissatisfied, somewhat dissatisfied, no opinion, somewhat satisfied, and completely satisfied.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Nikan Hospital

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Shahid Beheshti University of Medical Sciences

Proportion provided by this source

80

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
Shahid Beheshti University of Medical Sciences

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Position
Associate Professor

Latest degree
Subspecialist

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available