

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### Evaluation of intra-ovarian injection of platelet-rich plasma in patients with poor ovarian response; a randomized controlled clinical trial

#### Protocol summary

##### Study aim

Determination of the effect of intra-ovarian injection of platelet-rich plasma in patients with poor ovarian response.

##### Design

A randomized clinical trial with control group, open label, two arm parallel group design of 200 patients. Randomization is performed using a computer-generated random assignment schedule for each patient. Sealed and numbered envelopes are used to conceal the treatment allocation until randomization.

##### Settings and conduct

Female infertility Clinic of ROYAN institute.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients with a history of at least one poor ovarian response; Age  $\leq 44$  years; BMI  $< 35$  kg/m<sup>2</sup>; FSH  $< 25$  IU/L; AMH  $< 1.2$  ng/ml. Exclusion criteria: Endocrine, autoimmune and hematological disorders; Genetic diseases and chromosomal disorders; History of cancer; Uterine anomalies; Endometriosis, severe adenomyosis, hydrosalpinx, fibromatous uterus.

##### Intervention groups

Intervention group: PRP injection will be done on day 8-12 of the menstrual cycle. PRP injection will be performed less than 15 minutes after its preparation by the surgeon and gynecologist. The injection will be done through the vagina, under ultrasound guidance and with a follicle puncture needle (Reproline medical GmbH, single lumen without flushing, 17 GAUGE, D-53359 Rheinbach, Germany). The injection is done under mild anesthesia and takes less than 15 minutes.

##### Main outcome variables

Antral follicles count, and serum level of antimullerin hormone

#### General information

##### Reason for update

##### Acronym

PRP-POR

##### IRCT registration information

IRCT registration number: **IRCT20080831001141N40**

Registration date: **2023-01-17, 1401/10/27**

Registration timing: **prospective**

Last update: **2023-01-17, 1401/10/27**

Update count: **0**

##### Registration date

2023-01-17, 1401/10/27

##### Registrant information

###### Name

Kiandokht Kiani

###### Name of organization / entity

Royan Institute

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2230 7960

###### Email address

kiandokht.kiani@royaninstitute.org

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-02-01, 1401/11/12

##### Expected recruitment end date

2024-03-15, 1402/12/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of intra-ovarian injection of platelet-rich plasma in patients with poor ovarian response; a

randomized controlled clinical trial

### Public title

Intra-ovarian injection of platelet-rich plasma in patients with poor ovarian response

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Patients with a history of at least one poor ovarian response Age  $\leq 44$  years BMI  $< 35$  kg/m<sup>2</sup> FSH  $< 25$  IU/L AMH  $< 1.2$  ng/ml

#### Exclusion criteria:

Endocrine, autoimmune and hematological disorders Genetic diseases and chromosomal disorders History of cancer Congenital uterine anomalies Endometriosis, severe adenomyosis, hydrosalpinx, fibromatous uterus

### Age

To **44 years** old

### Gender

Female

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **200**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Block randomization method is designed by epidemiologist using STATA software version 13 and the number of blocks considered is 8. The random allocation list for patients is solely available to the epidemiologist. In order to hide the random allocation process, a total of 200 envelopes are prepared, and only the methodologist has been aware of table of random numbers. When the doctor declared the patient's eligibility, the methodologist provided the doctor with the envelope. The group will be selected and based on the type of group mentioned in the envelope.

### 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 Royan Institute

##### Street address

Royan Institute, Number 12, East Hafez Avenue, Banihashem Street, Resalat Highway.

#### City

Tehran

#### Province

Tehran

#### Postal code

148- 16635

#### Approval date

2022-12-20, 1401/09/29

#### Ethics committee reference number

IR.ACECR.ROYAN.REC.1401.089

## Health conditions studied

### 1

#### Description of health condition studied

Decreased ovarian reserve

#### ICD-10 code

N97.9

#### ICD-10 code description

Female infertility, unspecified

## Primary outcomes

### 1

#### Description

Increased ovarian reserve: increased number of antral follicles, and increased levels of antimullerin hormone.

#### Timepoint

6-8 weeks after intraovarian injection of platelet-rich plasma

#### Method of measurement

Doppler ultrasound and blood test

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: PRP injection will be done on day 8-12 of the menstrual cycle. PRP injection will be performed less than 15 minutes after its preparation by the surgeon and gynecologist. The injection will be done through the vagina, under ultrasound guidance and with a follicle puncture needle (Reproline medical GmbH, single lumen without flushing, 17 GAUGE, D-53359 Rheinbach, Germany). The injection is done under mild anesthesia and takes less than 15 minutes.

#### Category

Treatment - Other

### 2

#### Description

Control group: no intervention is done for the patients of

this group.

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Infertility Center of ROYAN

**Full name of responsible person**

Mehri Mashayekhy

**Street address**

Royan Institute, Number 12, East Hafez Avenue,  
Banihashem Street, Resalat Highway.

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**Email**

dr.mashayekhy@yahoo.com

**Web page address**

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

ROYAN Institute

**Full name of responsible person**

Parvaneh Afsharian

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**Email**

pafshar@royaninstitute.org

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

ROYAN Institute

**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**

Other

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

ROYAN Institute

**Full name of responsible person**

Mehri Mashayekhy

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Gynecology and Obstetrics

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**Person responsible for scientific inquiries**

**Contact**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Clinical study report (published article)

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

After the publication of the article

**To whom data/document is available**

Available to the public.

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

Scientific use by citing the source.

**From where data/document is obtainable**

Dr. Mehri Mashayekhy Email:  
dr.mashayekhy@yahoo.com

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

Request via e-mail

**Comments**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

ROYAN Institute

**Full name of responsible person**

Mehri Mashayekhy

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