

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 ≤ 44 years; BMI < 35 kg/m²; 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 ≤ 44 years BMI < 35 kg/m² 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.

City

Tehran

Province

Tehran

Postal code

148- 16635

Phone

+98 21 2356 2647

Fax

+98 21 2230 6481

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

Street address

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

City

Tehran

Province

Tehran

Postal code

148- 16635

Phone

+98 21 2356 2674

Fax

+98 21 2230 6481

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

Street address

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

City

Tehran

Province

Tehran

Postal code

148- 16635

Phone

+98 21 2356 2647

Fax

+98 21 2230 6481

Email

dr.mashayekhy@yahoo.com

Person responsible for scientific 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

Street address

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

City

Tehran

Province

Tehran

Postal code

148- 16635

Phone

+98 21 2356 2647

Fax

+98 21 2230 6481

Email

dr.mashayekhy@yahoo.com

dr.mashayekhy@yahoo.com

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

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

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

City

Tehran

Province

Tehran

Postal code

148- 16635

Phone

+98 21 2356 2647

Fax

+98 21 2230 6481

Email