Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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.

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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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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

Name of organization / entity

ROYAN Institute

Full name of responsible person

Mehri Mashayekhy

Position

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Latest degree

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Person responsible for updating data

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