

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Evaluation of intra-ovarian injection of platelet-rich plasma in patients with premature ovarian insufficiency; a clinical trial

Protocol summary

Study aim

Determination of the effect of intra-ovarian injection of platelet-rich plasma in patients with premature ovarian insufficiency.

Design

A clinical trial without control group, without blinding, phase 3, on 54 patients.

Settings and conduct

Female infertility Clinic of ROYAN institute.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients with premature ovarian insufficiency according to european society of human reproduction and embryology (ESHRE) guideline; Body mass index <35 Kg/m²; Normal karyotype; Normal fragile X messenger ribonucleoprotein 1 (FMR1) gene. Exclusion criteria: Endocrine, autoimmune and hematological disorders; Genetic diseases and chromosomal disorders; History of cancer; Uterine anomalies; Endometriosis, severe adenomyosis, hydrosalpinx, and fibromatous uterus.

Intervention groups

Intervention group: Platelet-rich plasma (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. The injection is done under mild anesthesia and takes less than 15 minutes.

Main outcome variables

Serum level of follicle-stimulating hormone (FSH). Serum level of Anti-Mullerian Hormone (AMH).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080831001141N41**

Registration date: **2023-02-08, 1401/11/19**

Registration timing: **registered_while_recruiting**

Last update: **2023-02-08, 1401/11/19**

Update count: **0**

Registration date

2023-02-08, 1401/11/19

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 premature ovarian insufficiency; a clinical trial

Public title

Intra-ovarian injection of platelet-rich plasma in patients with premature ovarian insufficiency

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with premature ovarian insufficiency according to European Society of Human Reproduction and Embryology (ESHRE) guideline Body mass index < 35 Kg/m² Normal karyotype Normal fragile X messenger ribonucleoprotein 1 (FMR1) gene

Exclusion criteria:

Endocrine, hematologic and autoimmune disorders Chromosomal and genetic abnormalities Cancer history Uterine anomalies Severe adenomyosis Endometriosis Hydrosalpinx Uterine fibromatosis

Age

To 40 years old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 54

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

A clinical trial without control group, without blinding, phase 3, on 54 patients.

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.1401.091

Health conditions studied

1

Description of health condition studied

Premature ovarian insufficiency

ICD-10 code

N97.9

ICD-10 code description

Female infertility, unspecified

Primary outcomes

1

Description

Serum level of follicle-stimulating hormone (FSH)

Timepoint

6-8 weeks after intra-ovarian injection of platelet-rich plasma

Method of measurement

Blood test

2

Description

Serum level of anti-mullerian hormone (AMH)

Timepoint

6-8 weeks after intra-ovarian injection of platelet-rich plasma

Method of measurement

Blood test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: Platelet-rich plasma (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. The injection is done under mild anesthesia and takes less than 15 minutes.

Category

Treatment - Other

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

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

ROYAN Institute

Full name of responsible person

Parvaneh Afsharian

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Royan Institute, Number 12, East Hafez Avenue,
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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

Name of organization / entity

ROYAN Institute

Full name of responsible person

Mehri Mashayekhy

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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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

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

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

Analytic Code

Not applicable

Data Dictionary

Not applicable