

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Evaluate the Safety and Feasibility of Intra-ovarian Injection of Autologous Adipose Derived Mesenchymal Stromal Cells (ADMSC) in Women With Premature Ovarian Failure (POF)

Protocol summary

Summary

Objective: Safety and tolerability and early evidence of effectiveness of intra-ovarian injection of adipose derived stromal cell in women with premature ovarian failure
Design: Study group: Nine POF patient in 3 groups (3 patient in each group), phase I. Blinding: No blinding, randomized single center. Sample size: Nine patients.
Setting and conduct: After trial description and obtaining informed consent, lipoaspiration will be performed and mesenchymal stem cells will be isolated and cultivated in clean room. Intra ovarian injection of 5 million ADSC will be performed in first group via a transvaginal sonographical guided intra ovarian injection. After establishing the safety of this step, the injection of 10 million of ADSC will be performed for second group and then the 3rd group will be transplanted with 15 million. All the patients will be followed within one year according to the protocol. At the end of one year after last patient transplantation the data with gathered and analyze. Inclusion/exclusion criteria: All women under 39 years old and normal karyotype who have not the exclusion criteria with premature ovarian failure Interventions: Intra ovarian injection of autologous ADSC Primary outcome: Safety, Secondary outcome: Early evidence of effectiveness.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201510271031N18**
Registration date: **2015-12-29, 1394/10/08**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-12-29, 1394/10/08

Registrant information

Name

Nasser Aghdami

Name of organization / entity

Royan Institute

Country

Iran (Islamic Republic of)

Phone

+98 21 2356 2000

Email address

nasser.aghdami@royaninstitute.org

Recruitment status

Recruitment complete

Funding source

Royan Institute

Expected recruitment start date

2015-12-06, 1394/09/15

Expected recruitment end date

2016-06-04, 1395/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluate the Safety and Feasibility of Intra-ovarian Injection of Autologous Adipose Derived Mesenchymal Stromal Cells (ADMSC) in Women With Premature Ovarian Failure (POF)

Public title

Study of autologous adipose derived stromal cell transplantation in women with POF

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Female; Age: 20-39; FSH>20; One year after POF diagnose; Normal karyotype
Exclusion criteria: Liposuction contraindication; Thyroid dysfunction; Immune system disease; Past history of cancer; Chemotherapy; Radiotherapy; HIV+; Hepatitis B or C; Severe endometriosis

Age

From **20 years** old to **39 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **9**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

No other design features

Secondary Ids

1

Registry name

clinicaltrials.gov

Secondary trial Id

NCT02603744

Registration date

2015-11-07, 1394/08/16

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Royan infertility institute

Street address

Royan institute, Eastern Hafez St,Northern
Banihashem St, 45 m Resalat highway

City

Tehran

Postal code

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

IR.ACECR.ROYAN.REC.1394.41

Health conditions studied

1

Description of health condition studied

Premature ovarian failure

ICD-10 code

E28.3

ICD-10 code description

Premature menopause NOS

Primary outcomes

1

Description

Number of patient with adverse event

Timepoint

One year after transplantation

Method of measurement

Adverse event report form

Secondary outcomes

1

Description

Number of antral follicle

Timepoint

Base line,1,2,4,8 and 12 weeks, 6 month and 1 year after
transplantation

Method of measurement

Sonography

2

Description

AMH serum level

Timepoint

Base line and 1 year after transplantation

Method of measurement

Laboratory test

3

Description

FSH serum level

Timepoint

Base line,1,2,4,8 and 12 weeks, 6 month and 1 year after
transplantation

Method of measurement

Laboratory test

4

Description

Antral follicle volume

Timepoint

Base line,1,2,4,8 and 12 weeks, 6 month and 1 year after
transplantation

Method of measurement

Sonography

5

Description

Menstruation recurrence rate

Timepoint

Base line, 1, 2, 4, 8 and 12 weeks, 6 month and 1 year after transplantation

Method of measurement

Questionary

6

Description

Pregnancy rate

Timepoint

One year after transplantation

Method of measurement

Beta-hCG serum level

Intervention groups

1

Description

Intervention: Intra ovarian injection of 1 cc of cell suspension of autologous ADSC in autologous serum

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Royan Institute

Full name of responsible person

Royan's Infertility Clinic

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Royan Institute

Full name of responsible person

Hamid Gourabi

Street address

Eastern Hafez St, Northern Banihashem St, 45 m
Resalat highway

City

Tehran

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

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Royan Institute

Full name of responsible person

Elham Mirzade

Position

M.D/ Researcher

Other areas of specialty/work

Street address

Eastern Hafez St, Northern Banihashem St, 45 m
Resalat highway

City

Tehran

Postal code

Phone

+98 21 2251 8388

Fax

Email

dr.mirzadeh@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Royan Institute

Full name of responsible person

Nasser Aghdami

Position

M.D, Ph.D

Other areas of specialty/work

Street address

Eastern Hafez St, Northern Banihashem St, 45 m
Resalat highway

City

Tehran

Postal code

Phone

+98 21 2251 8388

Fax

Email

nasser.aghdami@royaninstitute.org

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Royan Institute

Full name of responsible person

Hoda Madani

Position

M.D/ Researcher

Other areas of specialty/work**Street address**

Eastern Hafez St,Northern Banihashem St, 45 m

Resalat highway

City

Tehran

Postal code**Phone**

+98 21 2251 8388

Fax

+98 21 2251 6465

Email

hoda62_m@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty