

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Evaluation of the safety and feasibility of infra ovarian injection of menstrual blood derived stem cells (MenSCs) in women with premature ovarian failure

Protocol summary

Study aim

Increased ovarian function and fertility in early menopausal patients (POF) using stem cells derived from menstrual blood

Design

The study will be done as clinical trial such the ovarian function of POF patients after cell therapy using menstrual blood stem cells in case group will be compared to that of control group without intervention. The selection will be done as nonrandomized. The number of patients in each group will be 15.

Settings and conduct

The eligible patients will study and sign the inform consent. After randomization these women will be divided into case or control group and the phases 1 and 2 of clinical trial will be started. The menstrual blood will be collected using divacup at day 1 or 2 of menstruation and stem cells will be isolated cultured and assessed in aspect of phenotype and no contamination in clean room of Avicenna Research Institute. The autologous cultured cells will be administrated into ovary of patients in Avicenna infertility Clinic.

Participants/Inclusion and exclusion criteria

1 - married woman 2 - over 20 and under 40 years 3 - normal karyotype 4 - premature ovarian failure and the amount of follicle stimulating hormone greater than 20 IU / ml and anti-muller hormone below 1 ng / ml 5-sperm analysis at least 15 million per ml Sperm and normal morphology 2% and spermatozoa (A + B) above 25%

Intervention groups

1-Thyroid deficiency 2- Immune system disease 3- Cancer history and chemotherapy and radiation therapy 4. Hepatitis B and C virus infection and HIV 5- Endometriosis Severe 6. History of ovarian surgery 7- Diabetes 8. Test disorder Electrolyte or liver

Main outcome variables

number and size of anteral follicles, FSH and LH levels,

Anti Mullerian hormone (ATH) level, ovary size, menstruation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180619040147N1**

Registration date: **2018-08-20, 1397/05/29**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-16, 1398/10/26**

Update count: **2**

Registration date

2018-08-20, 1397/05/29

Registrant information

Name

Maryam Darzi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2020

Email address

m.darzi@ari.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-11, 1397/04/20

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the safety and feasibility of infra ovarian injection of menstrual blood derived stem cells (MenSCs) in women with premature ovarian failure

Public title
Evaluation of the safety and feasibility of infra ovarian injection of menstrual blood derived stem cells (MenSCs) in women with premature ovarian failure

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 got married woman normal karyotype FSH more than 20 IU/ml anti mullerian hormone; less than 1 ng/ml spermogram: more than 15 million/ml, normal morphology more than 2%, sperm motility (A+B) more than 25% anteral follicles: less than 5
Exclusion criteria:
 thyroid dysfunction immune disorders history of cancer, chemotherapy and radiotherapy infected by hepatitis B,C or HIV severe endometriosis history of ovarian surgery diabetes dysfunction of electrolyte or liver tests psychological problem like depression, high stress an anxiety

Age
From **20 years** old to **40 years** old

Gender
Female

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Not randomized

Randomization description

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

ACECR Biomedical Research Ethics Committee

Street address

1270, Secretariat of the Ethics Committee of ACECR, Deputy Director of Research and Technology, Headquarters of ACECR, Opposite the main door of Tehran University, Enghelab Street, Tehran

City

Tehran

Province

Tehran

Postal code

1936773493

Approval date

2018-05-06, 1397/02/16

Ethics committee reference number

IR.ACECR.REC.1397.001

Health conditions studied

1

Description of health condition studied

premature ovarian failure

ICD-10 code

E28.31

ICD-10 code description

Premature menopause

Primary outcomes

1

Description

number and diameter of anteral follicles, FSH level, AMH level, ovary volume, menstruation

Timepoint

3 months, 6 months and one year after cell administration

Method of measurement

sonography, embryologic evaluation, biochemical assays

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group includes 15 patients with premature ovarian failure that will be treated by stem cell injection.

Category

Treatment - Other

2

Description

Control group: includes 15 patients with premature ovarian failure that will not receive any intervention and their biochemical parameters, sonographic and embryologic data will be compared with intervention group.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Avicenna Infertility Clinic
Full name of responsible person
Somaieh Kazemnejad
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No 97, Beginning of Yakhchal Street, Shariati Ave.
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iranian academic center for education culture and research
Full name of responsible person
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Avicenna Research Institute, Shahid Beheshti University, Shahid Chamran Highway, Tehran, Iran
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iranian academic center for education culture and research
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
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Somaieh kazemnejad
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Latest degree

Ph.D.

Other areas of specialty/work

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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

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

Informed Consent Form

No - There is not 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