

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Evaluating the effects of allogeneic transplantation of umbilical cord-derived mesenchymal stem cells combination with in vitro activation (IVA) technique on improvement of ovarian function and fertility outcomes in women with premature ovarian failure (POF)- Clinical trials phase I

Protocol summary

Study aim

Evaluating the effects of allogeneic transplantation of umbilical cord- derived mesenchymal stem cells combination with in vitro activation (IVA) technique on improvement of ovarian function and fertility outcomes in women with premature ovarian failure

Design

Clinical trial phase I without control group on 10 patients

Settings and conduct

Isolation and expansion of stem cells: Motahari hospital clean room in Iran University of Medical Sciences
Implantation of stem cells and invitro activation operation: Razi hospital in Guilan University of Medical Sciences, Ghaem international hospital

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Women aged 18 to 40 years old; Normal karyotyping female; Diagnosed with Premature Ovarian Failure: Serum FSH > 20 IU/L, AMH < 0.3 ng /mL; Normal TSH; Agree to sign the designed consent for the study. Exclusion Criteria: Thyroid dysfunction; Immunological Conditions; Past history of malignancy/chemotherapy/radiotherapy; Infectious diseases: HIV+, hepatitis B+, C+; Abnormal karyotype; Previous surgical management of ovarian pathology; Severe endometriosis; Breast cancer, ovarian cancer; Severe pulmonary, kidney and hematological disease, diabetes (type I,II), Severe anemia (Hemoglobin <8 g/dL).

Intervention groups

Transplantation of of umbilical cord- derived mesenchymal stem cells into ovaries combination with in vitro activation (IVA) technique

Main outcome variables

FSH serum level, AMH serum level, Estradiol serum level,

Menstrual cycle, Menopausal symptoms, Number and size of ovarian follicles, Endometrial thickness, Natural conception rate or consequent assisted reproductive techniques (ART)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211021052828N1**

Registration date: **2021-11-14, 1400/08/23**

Registration timing: **prospective**

Last update: **2021-11-14, 1400/08/23**

Update count: **0**

Registration date

2021-11-14, 1400/08/23

Registrant information

Name

Elham Vojoudi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3376 4270

Email address

elhamvojoodi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-16, 1400/09/25

Expected recruitment end date

2023-08-16, 1402/05/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effects of allogeneic transplantation of umbilical cord- derived mesenchymal stem cells combination with in vitro activation (IVA) technique on improvement of ovarian function and fertility outcomes in women with premature ovarian failure (POF)- Clinical trials phase I

Public title

The Safety and Efficacy study of IVA technique Combined Stem Cell Therapy (IVASc) in Patients With Premature Ovarian Failure (POF)

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Normal karyotyping female Diagnosed with Premature Ovarian Failure: Serum FSH > 20 IU/L, AMH < 0.3 ng /mL
Normal TSH Agree to sign the designed consent for the study women aged 18 to 40 years old

Exclusion criteria:

Thyroid dysfunction Immunological Conditions Past history of malignancy/chemotherapy/radiotherapy Infectious diseases: HIV+, hepatitis B+, C+ Abnormal karyotype Previous surgical management of ovarian pathology Severe endometriosis Breast cancer, ovarian cancer Severe pulmonary, kidney and hematological disease, diabetes (type I,II), ... Severe anemia (Hemoglobin <8 g/dL)

AgeFrom **18 years** old to **40 years** old**Gender**

Female

Phase

1

Groups that have been masked

No information

Sample sizeTarget sample size: **10****Randomization (investigator's opinion)**

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Guilan University of Medical sciences

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Ershad St, Ansari Blv, Rasht Town

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Guilan

Postal code

417861311

Approval date

2021-10-13, 1400/07/21

Ethics committee reference number

IR.GUMS.REC.1400.325

Health conditions studied**1****Description of health condition studied**

Premature Ovarian Failure (POF)

ICD-10 code

E28.3

ICD-10 code description

Primary ovarian failure

Primary outcomes**1****Description**

Get regular periods naturally

Timepoint

Before intervention and 3, 6 and 12 months after intervention

Method of measurement

consultation

2**Description**

Decrease FSH serum level

Timepoint

Before intervention and 3, 6 and 12 months after intervention

Method of measurement

Serum level of hormone

3**Description**

Increase Estradiol serum level

Timepoint

Before intervention and 3, 6 and 12 months after intervention

Method of measurement

Serum level of hormone

4**Description**

Increase AMH serum level

Timepoint

Before intervention and 3, 6 and 12 months after intervention

Method of measurement

Serum level of hormone

5**Description**

, Increase of number and size of ovarian follicles

Timepoint

Before intervention and 3, 6 and 12 months after intervention

Method of measurement

, Sonography of follicle number and size

6**Description**

افزایش ضخامت اندومتر

Timepoint

Before intervention and 3, 6 and 12 months after intervention

Method of measurement

Sonography of endometrial thickness

7**Description**

Natural conception or conceive Assisted reproductive technology (ART)

Timepoint

Before intervention and 3, 6 and 12 months after intervention

Method of measurement

Consultation

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Invitro activation (IVA) and stem cell transplantation

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ghaem international hospital

Full name of responsible person

Dr. Marieh Mehrafza

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Shahid Eftekhari Blv.

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2**Recruitment center****Name of recruitment center**

Razi University Hospital

Full name of responsible person

Dr. Elham Vojoudi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mehr medical Institute

Full name of responsible person

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marzieh.mehrafza@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mehr medical Institute

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Dr. Elham Vojoudi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Tissue Engineering

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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

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

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

make this available

Data Dictionary

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