Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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+98 13 3376 4270

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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/cemotherapy/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)
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
1
Groups that have been masked
No information
Sample size
Target 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
Street address
Ershad St, Ansari Blv, Rasht Town
City
Rasht
Province
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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mehr medical Institute
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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
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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Person responsible for updating data

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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