

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Investigating the efficacy of exosomes derived from umbilical cord mesenchymal stem cells in treating infertility in women with chemotherapy or radiotherapy-induced ovarian failure

#### Protocol summary

##### Study aim

The production of exosome for treatment of ovarian failure in females treated with chemotherapy drugs or radiotherapy

##### Design

This is a non-blinded clinical trial that will be conducted on 10 eligible women with ovarian failure and the patients will be included in the intervention group.

##### Settings and conduct

This non-blinded study will be conducted in Motazadi Hospital, Kermanshah. After separating the mesenchymal stem cells from the placenta and checking the specific cell markers, the stem cells are cultured. In the following, the desired exosomes are isolated and their characteristics, including the presence of surface markers, are also examined. Then the obtained exosome precipitate is dissolved in PBS and frozen at -80°C until use. After the exosome injection is complete, and over the desired period of time, various assessments will be conducted to evaluate factors related to follicular growth, hormonal balance, and other ovarian condition improvements in these individuals

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Informed consent; Women with ovarian failure undergoing chemotherapy or radiotherapy; Follicle-Stimulation Hormone less more 10 mIU/mL; Normal infectious tests ( HBS Ag, HIV, VDRL,....) Exclusion criteria: History of any type of immunotherapy in the medical record; Thin endometrium; Organic diseases of the endometrium; Hydrosalpinx endometriosis stage 3 or 4; Asherman syndrome; Chromosomal disorders of couples; Immune system diseases including rheumatoid arthritis and thyroid autoimmunity during the last three months

##### Intervention groups

En The intervention group will receive one exosome unit equal to 200 µg of protein intraovarian. Exosomes are

derived from umbilical cord mesenchymal stem cells. There is no control group.

##### Main outcome variables

Fever and chills

#### General information

##### Reason for update

Mistake in data entry Adding patients undergoing radiotherapy

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130812014333N232**

Registration date: **2024-11-19, 1403/08/29**

Registration timing: **registered\_while\_recruiting**

Last update: **2026-05-28, 1405/03/07**

Update count: **2**

##### Registration date

2024-11-19, 1403/08/29

##### Registrant information

###### Name

Feizollah Foroughi

###### Name of organization / entity

kermanshah University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 83 1821 4653

###### Email address

fforoughi@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-10-06, 1403/07/15

**Expected recruitment end date**

2025-02-19, 1403/12/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigating the efficacy of exosomes derived from umbilical cord mesenchymal stem cells in treating infertility in women with chemotherapy or radiotherapy-induced ovarian failure

**Public title**

The effect of exosomes derived from umbilical cord stem cells on infertility in women with ovarian failure

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

informed consent Women with POI undergoing chemotherapy or radiotherapy FSH more than 10 mIU/mL Normal infectious tests (VDRL, HCV, HBS Ag, HIV)

**Exclusion criteria:**

History of any type of immunotherapy in the medical record Thin endometrium Organic diseases of the endometrium Hydrosalpinx endometriosis stage 3 or 4 Asherman syndrome Chromosomal disorders of couples Immune system diseases including rheumatoid arthritis and thyroid autoimmunity during the last three months

**Age**

No age limit

**Gender**

Female

**Phase**

1

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: 15

**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**

Ethics committee of Kermanshah University of Medical Sciences

**Street address**

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Approval date**

2024-07-24, 1403/05/03

**Ethics committee reference number**

IR.KUMS.REC.1403.199

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

Premature ovarian failure

**ICD-10 code**

N97.0

**ICD-10 code description**

Female infertility associated with anovulation

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

Fever and chills

**Timepoint**

End of study

**Method of measurement**

Ask the patient

**Secondary outcomes**

empty

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

The intervention group will receive one exosome unit equal to 200 µg of protein intraovarian. Exosomes are derived from umbilical cord mesenchymal stem cells. There is no control group.

**Category**

N/A

**Recruitment centers**

## 1

### Recruitment center

**Name of recruitment center**

Motazadi Hospital

**Full name of responsible person**

Dr. Sahar Rashidi

**Street address**

Motazedi Hospital, Ferdowsi Square

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6718814474

**Phone**

+98 83 3724 6351

**Email**

sadar.rashidi@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. Cyrus Jalili

**Street address**

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

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**Phone**

+98 83 3836 0014

**Email**

cjalili@kums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Kermanshah University of Medical Sciences

**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**

Academic

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. kamran Mansouri

**Position**

Member of the faculty of Kermanshah University of Medical Sciences

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Molecular medicine

**Street address**

Medical Biology Research Center, Faculty of Medicine, Nurse Blvd.

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kamranmansouri@gmail.com

## Person responsible for scientific inquiries

### Contact

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Kermanshah University of Medical Sciences

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**Position**

Member of the academic staff of Kermanshah University of Medical Sciences

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Molecular medicine

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## Person responsible for updating data

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Kermanshah University of Medical Sciences

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**Email**

kamranmansouri@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no further information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available