Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of using mesenchymal stem cell exosomes in the treatment of infertility in patients with Poor Ovarian Response

Protocol summary

Study aim
The aim of this study was to evaluate the effect of mesenchymal stem cell exosomes on improving fertility in women with Poor Ovarian Response (POR) or reduced ovarian reserve.

Design
Randomized, single-blind, active-controlled clinical trial with parallel design

Settings and conduct
The study location is Fatemeh Hospital, Hamadan. Participants in this study will have the problem of Poor Ovarian Response (POR) or reduced ovarian response. If they meet the inclusion criteria and give informed consent, they will be included in the study. Their demographic information will be recorded in a questionnaire and divided into two intervention and control groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Diagnosis: Women with Poor Ovarian Response (POR) History of infertility: At least one year of infertility Consent: Obtaining written informed consent from patients Exclusion criteria: Age less than 20 or more than 35 years History of infertility less than one year

Intervention groups
Intervention group: 15 eligible patients; receive 100 to 200 micrograms of exosome protein by intraovarian injection (under ultrasound guidance). Assessments will be performed in the next cycle and 3 to 6 months after injection. Control group: 15 eligible patients; similar to the intervention group, intraovarian injection (under ultrasound guidance) of phosphate buffered saline (PBS) as a placebo to maintain blinding. Assessments are exactly the same as the intervention group.

Main outcome variables
Pregnancy - Serum Anti-Mullerian Hormone (AMH) Levels

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251118068036N4**
Registration date: **2026-06-11, 1405/03/21**
Registration timing: **registered_while_recruiting**

Last update: **2026-06-11, 1405/03/21**
Update count: **0**

Registration date
2026-06-11, 1405/03/21

Registrant information

Name
omid ghorbani

Name of organization / entity

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Iran (Islamic Republic of)

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+98 81 3131 0000

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ghorbaniomid213@gmail.com

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-05-13, 1405/02/23

Expected recruitment end date
2027-05-13, 1406/02/23

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of using mesenchymal stem cell exosomes in the treatment of infertility in patients with Poor Ovarian Response

Public title
Studying the effect of mesenchymal stem cell exosomes on infertility treatment in patients with poor ovarian response (POR).
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis: Women with Poor Ovarian Response (POR) History of infertility: At least one year of infertility history Consent: Obtaining written consent from patients.
Exclusion criteria:
Age less than 20 or more than 35 years old History of infertility for less than one year
Age
From **20 years** old to **35 years** old
Gender
Female

Phase
1
Groups that have been masked

- Participant

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization method was clarified in the study protocol as follows: Participants were allocated to two intervention and control groups in a 1:1 ratio using a block randomization method. The random sequence was generated using Random Allocation Software and the blocks were considered as 4 and 6 variables. The allocation sequence was kept by an independent person from the study team in sealed, numbered, and opaque envelopes to ensure allocation concealment. Also, in the control group, a placebo with the same appearance and administration method as the main intervention was used. In the control group, the placebo (PBS solution without exosome) with the same appearance, volume, and administration method as the main intervention was received intraovarianly.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study will be conducted in a single-blind manner. In this regard, patients (participants) will be unaware of the type of drug they receive (exosomes or placebo). Also, the person responsible for evaluating the outcomes and collecting clinical data will be unaware of the patient grouping (intervention or control). This is done to reduce bias due to knowledge of the type of treatment received in the study results. It should be noted that due to the nature of the intervention, researchers who directly prescribe the intervention will be aware of the patient grouping
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Hamadan University of Medical Sciences
Street address
Shahid Fahmideh Street
City
Hamadan
Province
Hamadan
Postal code
6517835678
Approval date
2026-03-14, 1404/12/23
Ethics committee reference number
IR.UMSHA.REC.1404.992

Health conditions studied

1

Description of health condition studied
Investigating the effect of using mesenchymal stem cell exosomes in the treatment of infertility in patients with Poor Ovarian Response (POR)
ICD-10 code
N97
ICD-10 code description
Female infertility

Primary outcomes

1

Description
pregnancy
Timepoint
3 to 6 months after exosome injection.
Method of measurement
Transvaginal ultrasound or assessment of return of menstrual cycle

Secondary outcomes

1

Description
Serum anti-Mullerian hormone (AMH) levels
Timepoint
Before treatment and 3 to 6 months after injection
Method of measurement

blood test

Intervention groups

1

Description

Intervention group: This group includes patients who are treated with mesenchymal stem cell exosomes.Number: 15 eligible patients who receive exosomes (100-200 micrograms of protein) intravaginally.Duration of treatment: One treatment followed by follow-ups 1 month later and 3-6 months after injection.

Category

Treatment - Drugs

2

Description

In order to maintain blinding of the study, a phosphate buffered saline (PBS) solution, which does not contain any exosomes, is used for the control group patients. This solution is prepared exactly the same as the original product in terms of its appearance (color and transparency), injection volume (completely similar to the volume of the exosome solution), and administration method (intraovarian injection under ultrasound guidance via the transvaginal route).All placebo solutions are prepared and standardized by the Research Center's Biological Products Production Unit under sterile conditions and under the supervision of the Quality Control Unit, and are delivered to the infertility clinic on the same day of the intervention.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Fatemeh Hospital, Hamadan
Full name of responsible person
Mahnaz Yavangi
Street address
Shahid Fahmideh Street
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6517835678
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Alireza Soltanian
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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
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Mahnaz Yavangi
Position
Faculty member, Hamadan University of Medical Sciences
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Access to data will be available immediately after the final article is published.

When the data will become available and for how long
Access to data will be available immediately after the final article is published

To whom data/document is available
All researchers, researchers and clinical experts will be allowed to access the data of this study.

Under which criteria data/document could be used
It will be welcomed to conduct extensive analysis on the data of this study along with the data of other studies to write meta-analysis review articles.

From where data/document is obtainable
For more information, please send an email to Dr. Mahnaz Yavangi. All correspondence will be addressed to yavangi@umsha.ac.ir

What processes are involved for a request to access data/document
After making a phone call and submitting a request via email, a final response will be sent within at least 1 month.

Comments