

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Evaluation of the effect of the autologous exosomes derived from menstrual blood mesenchymal stem cells on implantation rate and prevention of miscarriage in patients with recurrent implantation failure

Protocol summary

Clinical pregnancy rate, Chemical pregnancy rate, Implantation rate, Live birth rate, Abortion rate

Study aim

Evaluation of the effect of the autologous exosomes derived from menstrual blood mesenchymal stem cells on implantation rate and prevention of miscarriage in patients with recurrent implantation failure

Design

Phase 1 and 2 randomized clinical trials with 22 patients in each group

Settings and conduct

This study will be performed in the infertility department of Imam Khomeini Hospital, Sari, Iran. The menstrual blood of patients with recurrent implantation failure is collected with a menstrual cup. Then the mesenchymal stem cells of the menstrual blood and the secreted exosomes are isolated and identified. Finally, autologous exosomes are injected into the uterus of patients in the intervention group with an Intrauterine insemination (IUI) catheter.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with recurrent implantation failure who have a history of at least three failures in the embryo transfer cycle or did not conceive after transferring at least ten good-quality embryos are studied. Patients should have a body mass index below 30 kg/m² and be in the age range of 20-40 years. Exclusion criteria: uterine abnormality in hysteroscopy, blood disorders, immunological disorders, hormonal disorders, and genetic abnormalities in parents.

Intervention groups

Forty-four patients who meet the inclusion criteria are divided into intervention and control groups. In the intervention group, 48 hours before frozen embryo transfer, 2 ml of exosomes derived from mesenchymal cells of menstrual blood are injected into the uterus with an IUI catheter. In the control group, exosome injection is not performed before frozen embryo transfer.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210228050535N2**

Registration date: **2023-01-03, 1401/10/13**

Registration timing: **prospective**

Last update: **2023-01-03, 1401/10/13**

Update count: **0**

Registration date

2023-01-03, 1401/10/13

Registrant information

Name

Amirali Khodashenas limoni

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3354 3353

Email address

s.khodashenas@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-04, 1402/01/15

Expected recruitment end date

2023-11-21, 1402/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the effect of the autologous exosomes derived from menstrual blood mesenchymal stem cells on implantation rate and prevention of miscarriage in patients with recurrent implantation failure

Public title
Exosome therapy in recurrent implantation failure

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Women with recurrent implantation failure who did not conceive after at least three embryo transfer cycles or after transferring at least ten good-quality embryos. Age between 20–40 years With Body Mass Index (BMI) under 30 kg/m²
Exclusion criteria:
Uterine abnormalities in hysteroscopy and hysterosalpingography Hematologic disorders Hormonal disorders Immunologic disorders Chromosomal abnormalities and genetic disorders in parents

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: **44**

Randomization (investigator's opinion)
Randomized

Randomization description
A random series of 44 is generated for patients who meet the study inclusion criteria. Patients are divided into intervention and control groups with a 1:1 ratio, so twenty-two patients are assigned to each group. Block randomization is performed by <https://www.sealedenvelope.com> with blocks of size 4.

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
Research Ethics Committees of Imam Hospital- Mazandaran University of Medical Sciences
Street address
Amir Mazandarani St
City
Sari
Province
Mazandaran
Postal code
4816633131
Approval date
2022-12-14, 1401/09/23
Ethics committee reference number
IR.MAZUMS.IMAMHOSPITAL.REC.1401.048

Health conditions studied

1

Description of health condition studied
Recurrent implantation failure
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Chemical pregnancy rate
Timepoint
Two weeks after embryo transfer
Method of measurement
Measurement of B-HCG

2

Description
Clinical pregnancy rate
Timepoint
Five weeks after embryo transfer
Method of measurement
Sonography

3

Description
Abortion rate
Timepoint
During pregnancy
Method of measurement
Sonography

Secondary outcomes

1

Description

Live birth rate
Timepoint
End of pregnancy
Method of measurement
Parturition

2

Description
Implantation rate
Timepoint
Six weeks after embryo transfer
Method of measurement
The number of gestational sacs divided by the number of transferred embryos

3

Description
Ongoing pregnancy
Timepoint
20th week of pregnancy
Method of measurement
Sonography

Intervention groups

1

Description
Intervention group: Forty-eight hours before the transfer of frozen embryos 2 ml of autologous exosomes derived from menstrual blood mesenchymal cells with a total protein of 20 µg/µl are injected into the uterus of patients in the intervention group through the IUI catheter.
Category
Treatment - Drugs

2

Description
Control group: Transfer of frozen embryos is performed without injection of autologous exosomes.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sari Imam Hospital
Full name of responsible person
Sepideh Peyvandi
Street address
Amir Mazandarani Blvd
City
Sari
Province
Mazandaran

Postal code
4816633131
Phone
+98 11 3434 3432
Email
dr_peyvandi@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Pedram ebrahimnejad
Street address
University of Medical sciences Moallem square,Sari.Iran.
City
Sari
Province
Mazandaran
Postal code
۴۸۱۵۷۳۳۹۷۱
Phone
+98 11 3325 7230
Email
pajhoheshi@mazums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Shabanali Khodashenas
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Biotechnology
Street address

Department of Medical Biotechnology, Faculty of
Advanced Medical Sciences, Payambar Azam
Complex

City

Sari

Province

Mazandaran

Postal code

4816934561

Phone

+98 11 3311 8945

Email

s.khodashenas@mazums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Shabanali Khodashenas

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Biotechnology

Street address

Department of Medical Biotechnology, Faculty of
Advanced Medical Sciences, Payambar Azam
Complex

City

Sari

Province

Mazandaran

Postal code

4816934561

Phone

+98 11 3311 8945

Email

s.khodashenas@mazums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Fatemeh zare taji

Position

Master's student

Latest degree

Master

Other areas of specialty/work

Medical Biotechnology

Street address

Department of Medical Biotechnology, Faculty of
Advanced Medical Sciences, Payambar Azam
Complex

City

Sari

Province

Mazandaran

Postal code

۴۸۱۵۷۳۳۹۷۱

Phone

+98 11 3354 3353

Fax

Email

f.zare.zt@gmail.com

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