

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Efficacy of exosome-impregnated paper patches in myringoplasty of patients with ruptured eardrums

Protocol summary

Study aim

Exosome-impregnated paper patches in myringoplasty of patients with eardrum rupture

Design

This is a non-blinded randomized clinical trial with a parallel design. This study will be conducted on at least 60 eligible patients and patients will be placed in the intervention group.

Settings and conduct

This study, which will be conducted at Imam Khomeini Hospital in Kermanshah, is non-blinded. The purification and isolation process of exosomes derived from umbilical cord mesenchymal stem cells will be performed at the Regenerative Medicine Center of Kermanshah University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Informed consent; Patients diagnosed with a perforated tympanic membrane; Age between 18-65 years; Patients who have no contraindications to regenerative therapy or stem cell-derived therapies and no history of autoimmune diseases or immunodeficiency conditions that could interfere with the effects of exosome therapy. Exclusion criteria: Patients with chronic middle ear infections who do not respond to standard treatments; Pregnant or breastfeeding women; b. ; Patients who are currently enrolled in other clinical trials involving regenerative or stem cell therapies or have a history of allergic reactions to stem cell-derived products or any of the therapeutic ingredients.

Intervention groups

In the intervention group, paper patches impregnated with exosomes derived from umbilical cord mesenchymal stem cells (UC-MSCs) will be used in myringoplasty surgery to treat patients with ruptured eardrums.

Main outcome variables

Repair of a ruptured eardrum

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N255**

Registration date: **2025-06-20, 1404/03/30**

Registration timing: **registered_while_recruiting**

Last update: **2025-06-20, 1404/03/30**

Update count: **0**

Registration date

2025-06-20, 1404/03/30

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-06-20, 1404/03/30

Expected recruitment end date

2025-12-21, 1404/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of exosome-impregnated paper patches in myringoplasty of patients with ruptured eardrums

Public title

Efficacy of exosome-impregnated paper patches in myringoplasty of patients with ruptured eardrums

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Informed consent Patients diagnosed with a perforated tympanic membrane Age between 18-65 years Patients who have no contraindications to regenerative therapy or stem cell-derived therapies and no history of autoimmune diseases or immunodeficiency conditions that could interfere with the effects of exosome therapy.

Exclusion criteria:

Patients with chronic middle ear infections who do not respond to standard treatments Pregnant or breastfeeding women Patients who are currently enrolled in other clinical trials involving regenerative or stem cell therapies or have a history of allergic reactions to stem cell-derived products or any of the therapeutic ingredients.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

N/A

Randomization description

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

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

2025-05-13, 1404/02/23

Ethics committee reference number

IR.KUMS.REC.1404.139

Health conditions studied

1

Description of health condition studied

Tympanic Membrane Perforation

ICD-10 code

H72

ICD-10 code description

Perforation of tympanic membrane

Primary outcomes

1

Description

Repair of a ruptured eardrum

Timepoint

One, three and six months after treatment

Method of measurement

Using tympanometry and audiometry

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, paper patches impregnated with exosomes derived from umbilical cord mesenchymal stem cells (UC-MSCs) will be used in myringoplasty surgery to treat patients with ruptured eardrums.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Dr. Hojat Sargazi

Street address

Imam Khomeini Hospital, Street of Naghliyah

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Kermanshah
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6718743161
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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

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. Taha Araghi
Position
A member of the university faculty

Latest degree
Specialist
Other areas of specialty/work
Ear, Nose, and Throat
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Name of organization / entity
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Position
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Person responsible for updating data

Contact

Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Hojat Sargazi
Position
Otolaryngology resident
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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