Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A Comparative Evaluation of the safety of acellular dermal matrix transplantation combined with adipose-derived mesenchymal stem cells versus standalone adipose-derived mesenchymal stem cell injection in the traetment of diabetic foot ulcers refractory to standard thrapies

Protocol summary

Study aim

To detrmine the effects of adipose-derived mesenchymal stem cells (ASC) and acellular dermal matrix (ADM) on the healing of diabetic foot ulcers in patients resistant to conventional treatments

Design

A clinical trial with the control group (before and after), with parallel groups, on 9 patients

Settings and conduct

In this study, 9 patients with treatment-resistant diabetic foot ulcers on the Wagner scale will be selected in Imam Reza hospital and divided into 3 groups. The injection will be repeated weekly for a duration of 4 weeks. The healing rate of diabetic foot ulcers is evaluated for 3 months. Blood samples will be collected before and after the intervention for gene analysis.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Type 1 or 2 Diabetes, Diabetic ulcer grade 1 to 4, Wound duration of more than 4 weeks, No receipt of biological medications; Exclusion Criteria: History of bone infection (osteomyelitis), Presence of exposed bone in the wound, Infected diabetic foot, Concurrent participation in other clinical trials

Intervention groups

Group 1: The locally administration of 1.5 x 10^6 adipose-derived stem cells (ASC) in days of 0, 7, 14, 21.
Group 2: The combination therapy of locally administration of 1.5 x 10^6 adipose-derived stem cells and acellular dermal matrix (ADM) in days of 0, 7, 14, 21.
Control group: the common treatment includes a combined treatment surgery, infection control,..

Main outcome variables

Wound size, The expression level of inflammatory genes IL-6 and IL-1

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130811014330N11**
Registration date: **2026-04-17, 1405/01/28**
Registration timing: **prospective**

Last update: **2026-04-17, 1405/01/28**
Update count: **0**

Registration date

2026-04-17, 1405/01/28

Registrant information

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Name of organization / entity
Mashhad University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-04-21, 1405/02/01

Expected recruitment end date

2026-07-21, 1405/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
A Comparative Evaluation of the safety of acellular dermal matrix transplantation combined with adipose-derived mesenchymal stem cells versus standalone adipose-derived mesenchymal stem cell injection in the traetment of diabetic foot ulcers refractory to standard thrapies

Public title
Investigation of the safety of allogeneic mesenchymal stem cell transplantation derived from adipose tissue in patients with diabetes

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Having a diabetic ulcer grade 1 to 4 according to Wagner's classification Having a single wound in the legs and extremities (fingers, soles, heels, on the toes) that has been at least 4 weeks old No smoking, alcohol and drug addiction Not receiving biological drugs Not having concurrent diseases such as cancers, vasculitis, kidney and liver failure, and heart failure that may cause problems in wound healing Vascular problems should not be observed in the wound (ankle-Brachial Index (ABI) should not be less than 0.7)

Exclusion criteria:
patients with history of osteomyelitis Presence of exposed bone within the wound area patient with infected diabetic foot ulcer Concurrent participation in other clinical trials Hemoglobin less than 10mg/dL

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **9**

Randomization (investigator's opinion)
Not randomized

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 Mashhad University of Medical Sciences

Street address
Qureshi Building of MUMS, University Street, Mashhad, Iran

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Mashhad

Province
Razavi Khorasan

Postal code
13944-91388

Approval date
2025-12-06, 1404/09/15

Ethics committee reference number
IR.MUMS.REC.1404.295

Health conditions studied

1

Description of health condition studied
diabetic foot ulcer

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The size of the wound

Timepoint
before traetment and days of 7, 14, 21, 28 and 3 months after traetment

Method of measurement
Digital camera

Secondary outcomes

1

Description
Expression of inflammatory gene IL-6

Timepoint
before the intervention and 3 months after the completion of intervention

Method of measurement
Gene expression level by Real time PCR by TaqMan probe

2

Description
Expression of inflammatory gene IL-1

Timepoint

before the intervention and 3 months after the completion of intervention

Method of measurement

Gene expression level by Real time PCR by TaqMan probe

Intervention groups

1

Description

Control group: The patients in the control group are treated with routine dressing. The common treatment for these patients is a combined treatment including surgery, infection control, etc., which is prescribed to the patient at the discretion of the treatment staff and depending on the type and severity of the wound.

Category

Other

2

Description

Intervention group 1: The locally administration of 1.5 x 10^6 adipose-derived stem cells (ADSCs) (allogen, viracell) in days of 0, 7, 14, 21 (In this group, the injection will be once a week for a month). Depending on the area of the wound, up to 5 ml (per session) of the cell by the surgeon is injected. It should be noted that the injection is done at several points of the edges of the wound so that the environment of the edge of the wound is properly covered. After that, the wound is bandaged with a wet silicone bandage. Wet silicone dressing is changed every three days.

Category

Treatment - Drugs

3

Description

Intervention group 2: The combination therapy of locally administration of 1.5 x 10^6 adipose-derived stem cells (ADSCs) (allogen, viracell) and acellular dermal matrix in days of 0, 7, 14, 21 (In this group, the injection will be once a week for a month). Depending on the area of the wound, up to 5 ml (per session) of the cell by the surgeon is injected. It should be noted that the injection is done at several points of the edges of the wound so that the environment of the edge of the wound is properly covered. After that, the wound is bandaged first with acellular dermal matrix and then with a wet silicone bandage. Wet silicone dressing is changed every three days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Hamid Reza Rahimi

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Imam Reza Hospital, Imam Reza Sq, Mashhad, Razavi Khorasan, Iran

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person
Hamid Reza Rahimi

Position
MD, Ph.D, assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Molecular medicine

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Web page address

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
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Clinical documentation will be published while maintaining confidentiality principles.

When the data will become available and for how long
One year after the end of sampling

To whom data/document is available
researchers working in academic and scientific institutions

Under which criteria data/document could be used
For further and supplementary research

From where data/document is obtainable
Dr Hamid Reza Rahimi

What processes are involved for a request to access data/document
Approved by the Research Committee of Mashhad University of Medical Sciences

Comments