Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the Safety and Efficacy of Transplanting an Injectable Hydrogel Carrier Laden with Mesenchymal Stem Cells for the Treatment of Patients with Diabetic Foot Ulcers: Phase 1/2 Clinical Trial (Semi-industrial Production of an Injectable MSC-Loaded Hydrogel Carrier for Chronic Wound Therapy)

Protocol summary

Study aim

Evaluation of the safety of the hydrogel carrier containing cells in the treatment of diabetic wounds Evaluation of the efficacy of the hydrogel carrier containing cells in the treatment of diabetic wounds Introduction of a novel therapeutic approach for chronic wound repair Assessment of the cost-effectiveness of hydrogel carrier containing cells therapy versus standard treatment Evaluation of the risk of late complications, including recurrent infection and amputation

Design

The study will be conducted as a randomized, controlled (interventional) Phase 1/2 clinical trial in 30 patients with diabetic wounds.

Settings and conduct

ACECR - Khorasan Razavi

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Adults with type 1 or type 2 diabetes and a non-healing foot ulcer of at least 4 weeks duration Diabetic foot ulcer classified as Wagner grade 1 or 2 Ankle–brachial index (ABI) ≥ 0.7 HbA1c < 12 % Wound area between 2 and 20 cm² No concurrent use of medications known to impair wound healing (e.g. corticosteroids, immunosuppressants, cytotoxic agents) Exclusion Criteria: Current use of corticosteroids, immunosuppressive drugs, or cytotoxic agents Pregnancy or breastfeeding Renal failure (serum creatinine > 3 mg/dL) Heart failure Uncontrolled systemic infection Age > 80 years Neuropathic disorders other than diabetic neuropathy Peripheral vascular disease Psychiatric illness or significant cognitive/functional impairment

Intervention groups

15 patients in the intervention group (treated with the hydrogel carrier containing cells plus standard therapy 15 patients in the control group (treated with standard care - advanced dressing)

Main outcome variables

wound surface size, pain, infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250302064900N1**
Registration date: **2025-05-29, 1404/03/08**
Registration timing: **prospective**

Last update: **2025-05-29, 1404/03/08**
Update count: **0**

Registration date

2025-05-29, 1404/03/08

Registrant information

Name

Halimeh Hassanzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3199 7451

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-06-22, 1404/04/01

Expected recruitment end date

2025-12-22, 1404/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Safety and Efficacy of Transplanting an Injectable Hydrogel Carrier Laden with Mesenchymal Stem Cells for the Treatment of Patients with Diabetic Foot Ulcers: Phase 1/2 Clinical Trial (Semi-industrial Production of an Injectable MSC-Loaded Hydrogel Carrier for Chronic Wound Therapy)

Public title

Evaluation of the Effect of an Injectable Hydrogel Carrier Containing Stem Cells on Diabetic Foot Ulcer Healing

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Individuals with type 1 or type 2 diabetes who have had non-healing wounds for at least four weeks Diabetic ulcer grade 1–2 on the Wagner scale; ankle-brachial index (ABI) ≥ 0.7; HbA_1c < 12 %; wound size 2–20 cm^2 No use of medications that may interfere with wound healing, such as corticosteroids, immunosuppressive agents, and cytotoxic drugs

Exclusion criteria:

Use of corticosteroids, immunosuppressive agents, and cytotoxic drugs Pregnancy and breast feeding Presence of renal failure (serum creatinine > 3 mg/dL); heart failure; uncontrolled systemic infection; neuropathic disorders other than diabetic neuropathy; peripheral vascular disease; and psychiatric illness or disability Age over 80 years

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Block Randomization In this study, randomization will be conducted using a block randomization method with an allocation ratio of 1:1 (equal distribution between the two groups). A total of 30 participants will be randomly assigned equally into two groups: Group A: Receiving treatment with cell-loaded hydrogel Group B: Receiving routine treatment To maintain balance in the number of participants in each group throughout the study, blocks of four (Block size = 4) were used. There are six possible permutations of the two treatments (A and B) within a four-subject block: AABB – ABAB – ABBA – BBAA – BABA – BAAB The sequence of block assignments was randomly generated using the Random Allocation Software. In total, 7 full blocks (4 participants each) and 1 final block (2 participants, with a 1:1 ratio of A to B) were designed to allocate all 30 participants. The randomly selected treatment sequences for each block are as follows: Block Number Randomized Treatment Sequence 1 ABAB 2 BAAB 3 AABB 4 BBAA 5 ABBA 6 BABA 7 AABB 8 (Final) AB The final allocation of participants will be carried out upon enrollment, based on the predefined sequences. Allocation concealment will be ensured by a person not involved in the execution of the study.

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 Mashhad ACECR in Biomedical Research

Street address

Azadi Square, Mashhad, Razavi Khorasan Province, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9177949367

Approval date

2025-02-22, 1403/12/04

Ethics committee reference number

IR.ACECR.JDM.REC.1403.008

Health conditions studied

1

Description of health condition studied

Patients with diabetic ulcers

ICD-10 code

E11.621

ICD-10 code description

Type 2 diabetes mellitus with foot ulcer

Primary outcomes

1

Description
wound surface size
Timepoint
On days 3, 7, and 14, and then monthly for up to one year
Method of measurement
Measuring tool

2

Description
wound healing rate
Timepoint
On days 3, 7, and 14, and then monthly for up to one year
Method of measurement
macroscopic evaluation

3

Description
Severity of wound pain
Timepoint
On days 3, 7, and 14, and then monthly for up to one year
Method of measurement
Pain score on a numeric rating scale

Secondary outcomes

1

Description
Survival Risk Percentage
Timepoint
day 365
Method of measurement
Plotting the survival curve

2

Description
Risk of Amputation
Timepoint
12 months after intervention
Method of measurement
Clinical Documentation

3

Description
Wound-Related Quality of Life Index
Timepoint
3 months after intervention
Method of measurement
Wound-QoL

Intervention groups

1

Description
Intervention group: Recipients of two million mesenchymal stem cells in a hydrogel carrier.
Category
Treatment - Drugs

2

Description
Control group: Recipients of standard treatment.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
ACECR- Khorasan Razavi
Full name of responsible person
Halimeh Hassanzadeh
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Stem Cells and Regenerative Medicine Research Group, ACECR, Azadi Sq.,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iranian academic center for education culture and research
Full name of responsible person
Masoud Golestanipour
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Iranian academic center for education culture and research
Proportion provided by this source
100
Public or private sector
Private
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
Iranian academic center for education culture and research
Full name of responsible person
Halimeh Hassanzadeh
Position
Assistant professor
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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
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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Part of the data - such as information related to the primary outcome or similar measures - can be shared.

When the data will become available and for how long

12 months after publication

To whom data/document is available

the researchers of accademic centers

Under which criteria data/document could be used

The applicant must submit a detailed proposal including the objectives, hypotheses, methodology, and the Statistical Analysis Plan (SAP). The proposal must be approved by the internal review committee (or ethics board) before any data are released. A commitment not to attempt to re-identify individual participants. The permissible scope of analyses (e.g., only descriptive analyses or pre-specified hypothesis tests). A prohibition on using the data for commercial purposes or product development without a separate agreement. An obligation to cite the data source in any publication or presentation. The applicant must submit the final analysis report and any resulting manuscripts or presentations to the core team within a specified timeframe (e.g., six months).

From where data/document is obtainable

Mahboubeh Kazemi

What processes are involved for a request to access data/document

Administrative review Scientific and ethics review Negotiation and signing of the Data Use Agreement (DUA) Data preparation and transfer setup

Comments