# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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**

h.hassanzadeh@acecr.ac.ir

**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
**Street address**
Stem Cells and Regenerative Medicine Research Group, ACECR, Azadi Sq.,
**City**
Mashhad
**Province**
Razavi Khorasan
**Postal code**
9177949367
**Phone**
+98 51 3199 7453
**Email**
malihehhassanzadeh748@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Iranian academic center for education culture and research
**Full name of responsible person**
Masoud Golestanipour
**Street address**
ACECR, Azadi Sq.,
**City**
Mashhad
**Province**
Razavi Khorasan
**Postal code**
9177949367
**Phone**
+98 51 3199 7401
**Email**
M.Golestanipour@gmail.com

**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
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Medical Biology
**Street address**
ACECR, Azadi Sq.,
**City**
Mashhad
**Province**
Razavi Khorasan
**Postal code**
9177949367
**Phone**
+98 51 3199 7453
**Email**
malihehhassanzadeh748@gmail.com

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Mashhad University of Medical Sciences
**Full name of responsible person**
Hadi Hosseinian
**Position**
Associate professor
**Latest degree**
Subspecialist
**Other areas of specialty/work**
Orthopedics
**Street address**
Azadi Sq.,
**City**
Mashhad
**Province**
Razavi Khorasan
**Postal code**
9177948564
**Phone**
+98 915 521 4159
**Email**
hoseinianh@mums.ac.ir

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Iranian academic center for education culture and research
**Full name of responsible person**
Mahboubeh Kazemi
**Position**
Assistant professor
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Medical Biology
**Street address**
Stem Cells and Regenerative Medicine Group, ACECR, Azadi Sq., Mashhad
**City**
Mashhad
**Province**
Razavi Khorasan
**Postal code**
۹۱۷۷۹۴۹۳۶۷
**Phone**
+98 51 3199 7453
**Email**
mahboobeh.kazemi@gmail.com

## 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**