

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Evaluation of Safety and Effectiveness of Expanded Allogenic Mesenchymal Stem Cells for the Treatment of Neuropathic Diabetic Foot Ulcer (Phase I/II Clinical Trial)

Protocol summary

Study aim

Evaluation of Safety and Effectiveness of Expanded Allogenic Mesenchymal Stem Cells for the Treatment of Neuropathic Diabetic Foot Ulcer

Design

In this study, 20 volunteers with Wagner Grade 2 diabetic foot ulcer will be recruited. This study will be a phase I and II clinical trial that the patients after standard treatment (debridement, infection control and off-loading) will be undergone Menstrual blood driven mesenchymal stem cell injection. The investigators will follow the patients for weekly up to first months, biweekly up to third months and monthly up to six months. The outcomes will be local and systemic reactions, wound area changes, and frequency of complete healing during study period.

Settings and conduct

This study will be conducted at Wound Healing Center of ACECR as a Phase I and II clinical trial in the volunteers with neuropathic diabetic foot wound.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: volunteers with chronic neuropathic diabetic foot ulcer (more than 6 weeks) with wound classification Wagner II, Suitable tissue perfusion ($ABI > 0.8$) and full informed consent for recruitment in the study. Exclusion Criteria: Suspected osteomyelitis, using corticosteroid or immuno-suppressor drug, chronic renal failure of hemodialysis, and charco Joint.

Intervention groups

Intervention group is the injection of allogenic mesenchymal stem cells in one session.

Main outcome variables

1) Local and systemic side effects 2) complete healing rate

General information

Reason for update

Due to the limitation of achieving healthy volunteers donating adipose tissue and the lack of GMP standardization by the clean room of Helal Medical Complex, the source of mesenchymal stem cells (MSCs) was changed to the commercial MSCs product (SinaBioMBcells) obtained from Avecina Institute.

Acronym

IRCT registration information

IRCT registration number: **IRCT20170612034485N2**
Registration date: **2018-02-11, 1396/11/22**
Registration timing: **prospective**

Last update: **2020-05-23, 1399/03/03**

Update count: **1**

Registration date

2018-02-11, 1396/11/22

Registrant information

Name

Gholamreza Esmaeeli Djavid

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6698 9110

Email address

djavid@ut.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-21, 1398/01/01

Expected recruitment end date

2020-08-22, 1399/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of Safety and Effectiveness of Expanded Allogenic Mesenchymal Stem Cells for the Treatment of Neuropathic Diabetic Foot Ulcer (Phase I/II Clinical Trail)

Public title
Allogenic stem cell in diabetic wound

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Chronic neuropathic diabetic foot ulcer (more than 6 weeks) with wound classification Wagner II full informed consent for recruitment in the study Suitable tissue perfusion (ABI>0.8) and normal flow of main arteries in lower extremities

Exclusion criteria:

Suspected osteomyelitis Using corticosteroid or immunosuppressor drug Chronic renal failure of Hemodialysis Charco Joint

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

Gender
Both

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
N/A

Randomization description

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

Biomedical Research Ethics Committee of Academic Center for Education, Culture and Research (ACECR)

Street address

ACECR Central Office, No. 1270 Enqelab Avenue

City
Tehran

Province
Tehran

Postal code
4364 - 14155

Approval date
2018-01-07, 1396/10/17

Ethics committee reference number
IR.ACECR.REC.1396.2

Health conditions studied

1

Description of health condition studied

Chronic diabetic foot Ulcer

ICD-10 code
E11.621

ICD-10 code description
Type 2 diabetes mellitus with foot ulcer

Primary outcomes

1

Description

Local and systemic side-effects

Timepoint

Every month up to month 6th

Method of measurement

Clinical examination

2

Description

Complete wound healing during study (at least 6 months)

Timepoint

Every month up to month 6th

Method of measurement

Clinical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: the volunteers who will receive allogenic mesenchymal stem cells in one session.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Wound Healing Center, ACECR of Tehran University of Medical Sciences Branch

Full name of responsible person

Gholamreza Esmaeeli Djavid

Street address

No. 66 Abourihan Street

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Web page address

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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

Seyed Mehdi Tabaie

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Grant name

Official Center of ACECR

Grant code / Reference number**Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iranian academic center for education culture and research

Proportion provided by this source

68

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

2

Sponsor

Name of organization / entity

Avecinna Research Insititue

Full name of responsible person

Somayeh Kazemnejad

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Avecinna Institute, Shahid Beheshti University,

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s.kazemnejad@ari.ir

Web page address

<https://www.avicenna.ac.ir/>

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Academic Center for Education, Culture and Research (ACECR)

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

Iranian academic center for education culture and research

Full name of responsible person

Gholamreza Esmaeeli Djavid

Position

MD-PhD/ Director

Latest degree

Ph.D.

Other areas of specialty/work

Biophysics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Iranian academic center for education culture and research

Full name of responsible person

Seyed Mehdi Tabaie

Position

Head of TUMS Branch of ACECR

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for updating data**Contact****Name of organization / entity**

Iranian academic center for education culture and

research

Full name of responsible person

Mehrangiz Toutouchi

Position

Physician

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All NA data will be accessible after publication.

When the data will become available and for how long

Time duration for access to the data will begin after publication for 2 years.

To whom data/document is available

Academic faculty member

Under which criteria data/document could be used

Systematic review and meta-analysis

From where data/document is obtainable

Contact with scientific correspondence of the project

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

via written request letter

Comments