Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

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

Protocol summary

Study aim

Evaluation of Safety and Effectivness of Expanded Allogenic Mesenchymal Stem Cells for the Treatment of Neuropatic 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 drived 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 neuropatic 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) ontained 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 Neuropatic 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 immuno-suppressor 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

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No. 66 Abourihan Street

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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
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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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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

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Head of TUMS Branch of ACECR
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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