Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jun 2026

Evaluation of efficacy of local injection of menstrual blood-derived mesenchymal stem cells SinaBioMBcell for the treatment of chronic neuropathic diabetic foot ulcer in a phase III double-blind randomized clinical trial

Protocol summary

Study aim
Evaluation of efficacy of local injection of menstrual blood stem cells SinaBioMBcell for the treatment of neuropathic diabetic foot ulcer

Design
The clinical trial includes a control group, two-arm parallel-group, double-blind randomized, phase III concludes 80 patients. block randomization was defined by using https://www.studyrandomizer.com/.

Settings and conduct
80 volunteer patients who refer to the Wound and Tissue Repair Research Center of the University of Medical Sciences, Academic Center for Education, Culture, and Research, will be examined by a dermatologist. After meeting the criteria, they will be divided into treatment and control groups. All of the patients will receive the same standard treatments, debridement of necrotic and infected tissues, and foam and Alginate bandages for reduction of the pressure. For the treatment group, cells will be injected into 5 spots (one into the middle and 4 into the margins) and for the control group, normal saline will be injected into the same spots. They will be under regular supervision for 48 hours and again evaluated on the first, second, fourth, sixth, and fifth week and again on third, fourth, fifth, and sixth-month post-injection

Participants/Inclusion and exclusion criteria
Chronic diabetic ulcers (more than 6 weeks) grade I-II Wagner, full-thickness ulcer, area of the wound between1-8 cm2, controlled blood sugar HbA1c less than 10, patient consent, age between 30-70, no desirable response to previous treatments, exit: osteomyelitis, high blood sugar, an area more than 8cm2

Intervention groups
Intervention: treated by injection of allogenic stem cell
Control: treated by injection of normal saline

Main outcome variables
Full closure of the wound, Rate of the closure, the time period of the closure, Side effect (pain, granuloma formation, infection, erythema, inflammation), Systematic reactions (fever, nausea, vomiting, allergy)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180619040147N5**
Registration date: **2021-03-29, 1400/01/09**
Registration timing: **prospective**

Last update: **2021-03-29, 1400/01/09**
Update count: **0**

Registration date
2021-03-29, 1400/01/09

Registrant information

Name
Maryam Darzi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2243 2020

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m.darzi@ari.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-14, 1400/01/25

Expected recruitment end date

2022-10-23, 1401/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of efficacy of local injection of menstrual blood-derived mesenchymal stem cells SinaBioMBcell for the treatment of chronic neuropathic diabetic foot ulcer in a phase III double-blind randomized clinical trial

Public title

Evaluation of efficacy of local injection of mesenchymal stem cells for the treatment of neuropathic diabetic foot ulcer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Chronic diabetic ulcers (more than 6 weeks) grade I-II Wagner classification without osteomyelitis Full thickness ulcer The size of the wound has to be between1-8 cm2 Controlled blood sugar (HbA1c less than 10) Patient's consent and clarification on whether they may be concluded in control or treatment group Non responsive ulcers to previous medications and treatments

Exclusion criteria:

Ulcers that are classified as grade 3-4 of Wagner classification or osteomyelitis has occurred Patients that don't meet the age criteria of the study High blood sugar levels The wounds that do not include full layers of skin. The wounds healed by other standard diabetic ulcers treatment methods

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization-In order to randomly assign 80 cases to the treatment group or control group, 10 blocks of 8 cases will be defined using "https://app.studyrandomizer.com". The treatment group and control group will be identified by codes A and B, respectively. In each block, The number of patients in the treatment group is equal to the number of patients in the control group, and The situation of each block is different from the other blocks

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is conducted as a double-blind clinical trial study. It indicates that the patients are blind to the treatment they are receiving and the specialist in charge of applying the treatment and collecting the data is also blind to the process.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

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

Street address

1270, Secretariat of the Ethics Committee of ACECR,Deputy Director of Research and Technology, Headquarters of ACECR, Opposite the main door of Tehran University, Enghelab Street, Tehran

City

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Province

Tehran

Postal code

1936773493

Approval date

2021-03-10, 1399/12/20

Ethics committee reference number

IR.ACECR.REC.1399.006

Health conditions studied

1

Description of health condition studied

Treatment of chronic neuropathic diabetic foot ulcers

ICD-10 code

E11.622

ICD-10 code description

Type 2 diabetes mellitus with foot ulcer

2

Description of health condition studied

Treatment of chronic neuropathic diabetic foot ulcers

ICD-10 code

E10.621

ICD-10 code description

Type 1 diabetes mellitus with foot ulcer

3

Description of health condition studied
Treatment of chronic neuropathic diabetic foot ulcers
ICD-10 code
E11-40
ICD-10 code description
Type 2 diabetes mellitus with diabetic neuropathy, unspecified

Primary outcomes

1

Description
Full thickness closure progress
Timepoint
Before treatment, the first, second, fourth, fifth, and sixth weeks and again on third, fourth, fifth, and sixth-months post-treatment
Method of measurement
On each evaluation period, the wounds will be measured with special devices like a ruler specialized for wound measurements.

Secondary outcomes

1

Description
Evaluation of local side effects (irritation, inflammation, pain, granulation, infection)
Timepoint
Before treatment, the first 48 hours, and again from the first week till week six of the study
Method of measurement
Clinical observation

2

Description
Evaluation of systematic side effects (skin sensitivity, fever, shivering, nausea, vomiting)
Timepoint
Before treatment, the first 48 hours, and again from the first week till week six of the study
Method of measurement
Clinical observation

3

Description
The rate of wound healing
Timepoint
Before treatment, then from first week till week six and then every month till six months post treatment
Method of measurement
Clinical observation

4

Description
Duration of complete wound healing
Timepoint
From week one, till week six, and then every month till six months post-treatment
Method of measurement
Clinical observation

5

Description
Side effects of choronic diabetic wounds on patients (the need of antibiotics prescription and Hospitalization)
Timepoint
From week one, till week six, and then every month till six months post-treatment
Method of measurement
Clinical observation

Intervention groups

1

Description
40 volunteer patients who refer to the Wound and Tissue Repair Research Center of the University of Medical Sciences, Academic Center for Education, Culture, and Research, will be examined by a dermatologist. After meeting the criteria, they will be divided into treatment and control groups. All of the patients will receive the same standard treatment, debridement of necrotic and infected tissues, controlling the infection, and foam and Alginate bandages for reduction of the pressure. For the treatment group, cells will be injected only once during the whole study into 5 spots (one into the middle and 4 into the margins). The bandages will then be applied, and the patients or their caretakers will be informed and educated on how to change the bandages by themselves. They will be under regular supervision for 48 hours and again evaluated on the first, second, fourth, sixth, and fifth week and again on third, fourth, fifth, and sixth-month post-injection. Cell product preparation: 10 healthy, married women of fertility age who have checked in Avicenna Infertility Center for their routine check-ups will be informed by a gynecologist. After informing them of the study and having their consents, on the second day of their menstruation cycle, their menstrual blood is collected by standard menstrual Diva-cups for 8-12 hours. Afterward, the samples will be placed in pre-prepared and coded tubes containing the culture medium and sent to the GMP grade clean room of Avicenna Research Institute. Mesenchymal cells will be separated and stored in the cell bank until the day of injection.
Category
Treatment - Other

2

Description
40 volunteer patients who refer to the Wound and Tissue Repair Research Center of the University of Medical Sciences, Academic Center for Education, Culture, and Research, will be examined by a dermatologist. After

meeting the criteria, they will be divided into treatment and control groups. All of the patients will receive the same standard treatment, debridement of necrotic and infected tissues, controlling the infection, and foam and Alginate bandages for reduction of the pressure. For the control group, normal saline will be injected only once during the whole study into 5 spots (one into the middle and 4 into the margins). The bandages will then be applied and the patients or their caretakers will be informed and educated on how to change the bandages by themselves. They will be under supervision for 48 hours and again evaluated on the first, second, fourth, sixth, and fifth week and again on third, fourth, fifth, and sixth-month post-injection

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Wound and tissue repair research center of the University of Medical Sciences Academic Center for Ed

Full name of responsible person

Gholamreza Esmaeil Javid

Street address

Enghelab St, South Flestein St, Nazari St, building No.17

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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

Mohammad-Reza Sadeghi

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Avicenna Research Institute, Shahid Beheshti University, Shahid Chamran Highway, Tehran, Iran

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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

Iranian academic center for education culture and research

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 Esmaeil Javid

Position

Assisstant professor

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Somaieh Kazemnejad

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Not applicable