Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 2026

Investigation of the therapeutic potential of fibroblast and adipose-derived mesenchymal stem cells loaded on nanofiber scaffolds for healing the diabetic foot ulcer in diabetic patients and comparison with common procedures.

Protocol summary

Study aim
Since the use of stem cells and diabetes disease are considered as research priorities of the national science foundation, this research tries to heal diabetic foot ulcer effectively by using the stem cells which loaded on nanofiber scaffolds.

Design
The sample size of the study is 20 which will be divided into control and intervention groups by simple randomization.

Settings and conduct
This study will be performed at Endocrine & Metabolism Research Center affiliated to Isfahan University of Medical Sciences. Diabetic patients who are suffering from diabetic foot ulcer will be divided into two completely matched groups. The control group will receive conventional treatment only. The intervention group will receive stem cells bandage in addition to usual treatment. The blinding will not be done in this research.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 21 to 65 years old, having diabetic foot wounds that have not recovered despite treatment during the past month, feeling pain while walking and resting, signature written consent. Exclusion criteria: Age over 65 years old, pregnancy or breastfeeding, the presence of septicemia, other systemic diseases in which the kidney is involved, hospitalization due to a serious illness in the past two months, severe malnutrition, the presence of foot ulcer due to all reasons except diabetes and any allergy to the compounds used in the cell culture process.

Intervention groups
Intervention group: Diabetic patients with foot ulcer who received stem cell therapy in addition to routine treatment. Control group: Diabetics patients with foot ulcer who only received routine treatment.

Main outcome variables
Wound size based on cm2; The distance that the patient can walk without pain; Biochemical markers including ALT, AST, Bilirubin, FBS, TG, Cholesterol, BUN, Cr

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190214042712N1**
Registration date: **2019-09-17, 1398/06/26**
Registration timing: **retrospective**

Last update: **2019-09-17, 1398/06/26**
Update count: **0**

Registration date
2019-09-17, 1398/06/26

Registrant information

Name
Amir Safi

Name of organization / entity

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Iran (Islamic Republic of)

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+98 31 4265 7800

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2015-09-23, 1394/07/01

Expected recruitment end date

2018-05-20, 1397/02/30

Actual recruitment start date

2015-09-23, 1394/07/01

Actual recruitment end date

2018-05-20, 1397/02/30

Trial completion date

2018-08-21, 1397/05/30

Scientific title

Investigation of the therapeutic potential of fibroblast and adipose-derived mesenchymal stem cells loaded on nanofiber scaffolds for healing the diabetic foot ulcer in diabetic patients and comparison with common procedures.

Public title

The use of stem cells loaded on nanofiber tissue scaffolds to repair the diabetic foot ulcer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 21 to 65 years old Having diabetic foot wounds that have not recovered despite a cure during the past month (2-7 cm) Feeling pain at rest and walking Signature written consent

Exclusion criteria:

Patients over 65 years old Pregnancy or breastfeeding The presence of septicemia Other systemic diseases in which the kidney is involved, such as cancer, autoimmune diseases, blood diseases, liver disease and ... Hospitalization due to serious illness in the past two months Severe malnutrition The presence of foot ulcer due to all reasons except for diabetes, for example, syphilis, tuberculosis, or fungal foot Any allergy to the compounds used in the cell culture process

Age

From **21 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Actual sample size reached: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization is done by a random number table.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib street, Isfahan, Iran

City

Isfahan

Province

Isfehan

Postal code

81746-73461

Approval date

2019-06-25, 1398/04/04

Ethics committee reference number

IR.MUI.REC.1395.4.078

Health conditions studied

1

Description of health condition studied

Diabetic foot ulcer

ICD-10 code

E14.5

ICD-10 code description

Diabetes mellitus with peripheral circulatory complications

Primary outcomes

1

Description

Wound size based on cm2

Timepoint

Before treatment and at every 1 and 2 weeks after treatment

Method of measurement

By multiplying the length of the wound by depth of the wounds

2

Description

The distance that the patient can walk without pain

Timepoint

Before treatment and at every 1 and 2 weeks after treatment

Method of measurement

Meter

3

Description
Biochemical markers including ALT, AST, Bilirubin, FBS, TG, Cholesterol, BUN, Cr
Timepoint
Before and after treatment
Method of measurement
Biochemical tests

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Diabetic patients with foot ulcer will receive stem cell therapy in addition to routine treatment. The stem cells will be loaded on nanofiber scaffolds in the central lab to prepare and then use the bandages. The treatment sessions will take one to two months, such that in each week one bandage will be put on the foot of patients topically. The patients are regularly visited twice in a week.
Category
Treatment - Other

2

Description
Control group: Diabetics patients with foot ulcer will only receive routine treatments including debridement, Prescribing antibiotics, wound cleaning, and normal dressing.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan Endocrine & Metabolism Research Center
Full name of responsible person
Rokhsareh Meamar
Street address
Isfahan University of Medical Sciences, Hezar Jarib street, Isfahan, Iran
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8174673461
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran National Science Foundation
Full name of responsible person
Nosratollah Zargham
Street address
33 NO, 5th alley., North Kargar Street.
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Tehran
Province
Tehran
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1439634665
Phone
+98 21 8216 1000
Fax
+98 21 8800 3981
Email
presidency@insf.org
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran National Science Foundation
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
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Rokhsareh Meamar
Position
Assistant Professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information
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
Undecided - It is not yet known if there will be a plan to make this available