

# 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 cm<sup>2</sup>; 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 4265 7800

##### Email address

st-safi.a@skums.ac.ir

#### 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

Isfahan

##### 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 cm<sup>2</sup>

#### 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

##### **City**

Isfahan

##### **Province**

Isfahan

##### **Postal code**

8174673461

##### **Phone**

+98 31 3668 0048

##### **Email**

meamar@pharm.mui.ac.ir

### **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.

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

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

##### **Latest degree**

Ph.D.

##### **Other areas of specialty/work**

Others

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Esfahan University of Medical Sciences

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Esfahan University of Medical Sciences

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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