

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Comparison the safety and efficacy of Adipose derived Stromal Cells - Seeded acellular dermal matrix and Adipose derived Stromal Cells injections in patients with diabetic foot ulcer resistant to standard care: Randomized clinical trial phase I/II

#### Protocol summary

##### Study aim

1- assessment of wound closure rate 2. Determine the number of dressings required for complete wound closure 3. Histologic and molecular assessments 4- Assessment the potential side effects

##### Design

Randomized, controlled, parallel group, phase I/II clinical trial in 30 patients and 6 months follow up

##### Settings and conduct

Patients suffering from diabetic ulcer referring to the Skin and Stem Cells will randomly receive Silicone dressing, ADM with adipose-derived stromal cell and silicone dressing, or adipose derived stromal cell injection alone. According to the intervention type, blinding is not relevant. Patients' wounds are evaluated once a week for up to 12 weeks or up to 1 week after complete closure in terms of efficacy and complications.

##### Participants/Inclusion and exclusion criteria

Inclusion: Age 18 -60, Type 1 or 2 diabetes, Ulcer size 2-20 cm<sup>2</sup>, Ulcer duration of more than 4 weeks and were not responsive to standard wound care, No clinical signs of infection, Serum creatinine <3 mg/dl, HbA1c <12%, ABI between 0.7 and 1.2 Exclusion: wound duration of >52 weeks without intermittent healing, ulcer probing to tendon, muscle, capsule or bone, radiation or chemotherapy, Known or suspected malignancy of ulcer, autoimmune connective tissue disease, topical growth factor within previous 30 days, Pregnant or breast feeding, immune system modulator drugs, allergy or known sensitivity to Gentamicin, Streptomycin or bovine collagen, wounds improving more than 20% over the 4-week run-in period of the trial using standard of care, patient taking Cox-2 inhibitors, HBV, HCV or HIV positive.

##### Intervention groups

Silicone dressing group, ADM with adipose-derived stromal cell and silicone dressing group, and adipose

derived stromal cell injection alone group

##### Main outcome variables

Safety; wound size; wound depth; wound closure time

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20080901001159N26**

Registration date: **2019-08-18, 1398/05/27**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-08-18, 1398/05/27**

Update count: **0**

##### Registration date

2019-08-18, 1398/05/27

##### Registrant information

##### Name

Mohamad Ali Nilforoushzadeh

##### Name of organization / entity

Skin and Stem Cell Research Center, Tehran  
University of Medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2220 5158

##### Email address

sdlrc@mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-07-23, 1398/05/01

**Expected recruitment end date**

2020-01-21, 1398/11/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison the safety and efficacy of Adipose derived Stromal Cells -Seeded acellular dermal matrix and Adipose derived Stromal Cells injections in patients with diabetic foot ulcer resistant to standard care: Randomized clinical trial phase I/II

**Public title**

Cell therapy in diabetic foot ulcer

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age 18 -60 Type 1 or Type 2 diabetes Able and willing to provide consent and agrees to comply with study procedures and follow-up evaluations Ulcer size 2-20 cm<sup>2</sup> Ulcer duration of more than 4 weeks, unresponsive to standard wound care No clinical signs of infection Serum creatinine <3 mg/dl HbA1c <12% ABI between 0.7 and 1.2

**Exclusion criteria:**

wound duration of >52 weeks without intermittent healing Index ulcer probing to tendon, muscle, capsule or bone Currently receiving radiation or chemotherapy Known or suspected malignancy of current ulcer Diagnosis of autoimmune connective tissue disease Use of biomedical/topical growth factor within previous 30 days Pregnant or breast feeding Taking medications considered to be immune system modulators Allergy or known sensitivity to Gentamicin, Streptomycin or bovine collagen Wounds improving more than 20% over the 4-week run-in period of the trial using standard of care. Patient taking Cox-2 inhibitors. HBV, HCV or HIV positive.

**Age**

From **18 years** old to **60 years** old

**Gender**

Both

**Phase**

1-2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization method: Simple Randomization unit: Individual stratified randomization is not included Randomization Tool: Random number box Allocation concealment: The cell product, cell or non cell based dressings are delivered to the physician with code numbers. Then the cell product or dressings will be placed on the patient's wound based on randomization

number box.

**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**

Ethics committee of Tehran University of Medical Sciences

**Street address**

Keshavarz st, Qods st, Central building of university, 6th floor, deputy for research and technology

**City**

Tehran

**Province**

Tehran

**Postal code**

1416613675

**Approval date**

2018-12-15, 1397/09/24

**Ethics committee reference number**

IR.TUMS.VCR.REC.1397.669

**Health conditions studied****1****Description of health condition studied**

diabetic foot ulcer

**ICD-10 code**

E08.621

**ICD-10 code description**

Diabetes mellitus due to underlying condition with foot ulcer

**Primary outcomes****1****Description**

Wound extent (cm<sup>2</sup>)

**Timepoint**

Before intervention, every week up to 1 month, and every month up to 6 months

**Method of measurement**

Image J software

## Secondary outcomes

### 1

#### Description

Safety

#### Timepoint

intervention start date up to 6 months

#### Method of measurement

Medical history and physical examination

## Intervention groups

### 1

#### Description

Intervention group: Silicone dressing (monlyke company) and ADM (Iranian tissue product company) with allogenic adipose-derived stromal cells, 1 million cells/cm<sup>2</sup> of wound, every 2 weeks till complete wound closure

#### Category

Treatment - Other

### 2

#### Description

Intervention group: allogenic adipose-derived stromal cells, 1 million cells/cm<sup>2</sup> of wound, every 2 week still complete wound closure

#### Category

Treatment - Other

### 3

#### Description

Control group: silicon foam (monlyke company), every 2 weeks till complete wound closure

#### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Skin and Stem cell Research Center

##### Full name of responsible person

Mohammad Ali Nilforooshzadeh

##### Street address

Maryam alley, Pasha Zahari st, South Kamranieh

##### City

Tehran

##### Province

Tehran

##### Postal code

1937957511

##### Phone

+98 21 2221 2537

##### Email

nilforoushzadeh@mui.ac.ir

##### Web page address

<http://skinstemcell.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

مرکز تحقیقات پوست و سلول های بنیادی دانشگاه علوم پزشکی تهران

##### Full name of responsible person

Mohammad Ali Nilforooshzadeh

##### Street address

No 4, Maryam Alley, South Kamraniye, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1937957511

##### Phone

+98 21 2221 2537

##### Email

nilforoushzadeh@mui.ac.ir

##### Web page address

<http://skinstemcell.ir/>

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

No

#### Title of funding source

Skin and Stem Cells Research Center of Tehran University of Medical Sciences

#### 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

Tehran University of Medical Sciences

##### Full name of responsible person

Amir Bajouri

##### Position

Clinical researcher

##### Latest degree

Medical doctor

##### Other areas of specialty/work

General Practitioner

##### Street address

Maryam alley, Pasha Zahari st, South Kamranieh

##### City

Tehran  
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16635148  
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**Email**  
bajouri\_md@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Mohammad Ali Nilforoushzadeh  
**Position**  
Associate Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Dermatology  
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sdlrc@mui.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Iranian academic center for education culture and  
research  
**Full name of responsible person**  
Amir Bajouri  
**Position**  
Clinical researcher  
**Latest degree**

Medical doctor  
**Other areas of specialty/work**  
General Practitioner  
**Street address**  
No 9, Shaghayegh alley, Banihashem st, Resalat Ave  
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Tehran  
**Province**  
Tehran  
**Postal code**  
16635148  
**Phone**  
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**Email**  
bajouri\_md@yahoo.com  
**Web page address**

## 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

Yes - There is a plan to make this available

### Title and more details about the data/document

All data will be shared after unidentifiable of the patients

### When the data will become available and for how long

6 months after paper publication

### To whom data/document is available

Academic researchers

### Under which criteria data/document could be used

In term of analysis the data related to study outcomes

### From where data/document is obtainable

bajouri\_md@yahoo.com

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

The request will be assessed by research committee of  
Skin and Stem cells research center which will be taken  
around 1-2 months

### Comments