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 assesments 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 cm2, 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)

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+98 21 2220 5158

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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 cm2 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 (cm2)
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/cm2 of wound, every 2 weeks till complete wound closure
Category
Treatment - Other

2

Description
Intervention group: allogenic adipose-derived stromal cells, 1 million cells/cm2 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
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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
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No 4, Maryam Alley, South Kamraniye, Tehran
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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
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Person responsible for scientific inquiries

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Position
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Other areas of specialty/work
Dermatology

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Person responsible for updating data

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Full name of responsible person
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General Practitioner

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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