Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of efficacy and safety of Sinaderm dermal substitute plus standard treatment (wet dressing) comparing standard treatment alone for healing chronic lower extremity diabetic ulcers

Protocol summary

Study aim

Evaluation of efficacy and safety of Sinaderm dermal substitute plus standard treatment (wet dressing) comparing standard treatment alone for healing chronic lower extremity diabetic ulcers

Design

parallel group, phase 3, parallel treatment-control clinical study. sample size is 68. The study is randomized and one-way blind. An online site (https://www.sealedenvelope.com) will be used to randomization.

Settings and conduct

The study will be performed in Center for the Study and Research of Diseases of the Skin and Leprosy. 68 volunteers will be selected and enrolled in the study after signing consent form. subjects will be enrolled to one of intervention groups acoording to the randomization list (Sinaderm dermal substitute plus standard treatment (wet dressing) comparing standard treatment alone). The evaluation will perform based on the Wagner calcification before the intervention and once a week for 8 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Signing the consent form for participation in the study patients with type I or II diabetes mellitus and neuropathy disorder 3 (defined by Michigan diabetic neuropathy score) At least 1, but no more than 2, partial thickness neuropathic ulcer (stage I and II as defined by Wagner staging system) located on the lateral foot, plantar arch, forefoot, , heel, or toe. Exclusion criteria: Patients with ulcers resulting from electrical, chemical, or radiation burns or venous insufficiency Patients with ulcers resulting from amputation Uncontrolled infection or necrosis or cellulitis at the site of the target ulcer Uncontrolled hyperglycemia (HbA1c > 10%) Pregnancy or lactating

Intervention groups

Intervention group: human fibroblast-derived dermal substitute(sinaderm) Control group: wet dressing by Normal saline

Main outcome variables

Percentage of change in wound area compared to baseline

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190210042676N7**
Registration date: **2020-05-19, 1399/02/30**
Registration timing: **prospective**

Last update: **2023-02-14, 1401/11/25**
Update count: **2**

Registration date

2020-05-19, 1399/02/30

Registrant information

Name

Aniseh Samadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 2220

Email address

a_samadi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2021-04-09, 1400/01/20

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of efficacy and safety of Sinaderm dermal substitute plus standard treatment (wet dressing) comparing standard treatment alone for healing chronic lower extremity diabetic ulcers

Public title
Evaluation of efficacy and safety of dermal substitute (Sinaderm)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Signing the consent form for participation in the study Men or women with type I or II diabetes mellitus and neuropathy disorder 3 (defined by Michigan diabetic neuropathy score) At least 1, but no more than 2, partial thickness neuropathic ulcer (stage I and II as defined by Wagner staging system) located on the lateral foot, plantar arch, forefoot, , heel, or toe The target ulcer have an area, after debridement between 3 and 25 cm2 The target ulcer has been present for at least 4 weeks at the time of the baseline visit
Exclusion criteria:
Patients with ulcers resulting from electrical, chemical, or radiation burns or venous insufficiency Patients with ulcers resulting from amputation Uncontrolled infection or necrosis or cellulitis at the site of the target ulcer Chronic renal insufficiency (serum creatinine > 2.5) Uncontrolled hyperglycemia (HbA1c > 10%) Administration of some medications (chemotherapy, immune suppressants, corticosteroids or radiotherapy) within past 30 days Pregnancy or lactating Heavy smokers
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **68**
Randomization (investigator's opinion)
Randomized
Randomization description
An online site (https://www.sealedenvelope.com) will be used to generate a randomized list of study groups. According to the random block method and considering the four blocks, 17 blocks will be produced for 68patients.
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
Research and Technology Dept, 6th floor, Central Organization of the University, Ghods St., Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2020-04-29, 1399/02/10
Ethics committee reference number
IR.TUMS.VCR.REC.1399.312

Health conditions studied

1

Description of health condition studied
Personal history of diabetic foot ulcer
ICD-10 code
Z86.31
ICD-10 code description
Personal history of diabetic foot ulcer

Primary outcomes

1

Description
Area of wound compared to baseline
Timepoint
Before the intervention and once a week for 8 weeks
Method of measurement
Checkered paper

Secondary outcomes

1

Description
The percentage of patients who responded 50% to

treatment

Timepoint

Once a week for 8 weeks

Method of measurement

counting the respounders

2

Description

Patients' satisfaction

Timepoint

Once a week for 8 weeks

Method of measurement

Questionnaire.Patent will declare his or her satisfaction in case of the compatibility of the dressings , its help to reduce the pain and also improving the wound using five-grade Likert scale (5= extremely satisfied, 4= very satisfied, 3= moderately satisfied, 2= slightly satisfied, 1= dissatisfied)

Intervention groups

1

Description

Intervention group: human fibroblast-derived dermal substitute(sinaderm) plus wet dressing. sinaderm will be inserted once or twice according to physician opinion and wet dressing will be inserted over it. wet dressing will be changed each 72 hours till complete wound healing.

Category

Treatment - Devices

2

Description

Control group: wet dressing by Normal saline which will be changed every 24 hours till complete wound healing.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

center for research and training in skin diseases and leprosy

Full name of responsible person

Aniseh Samadi

Street address

No. 415, Shahid Naderi (Soheil) St. Taleqani Ave.

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1416613675

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Email

dermalab@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

SinaCell Knowledge-based production Company

Full name of responsible person

Maryam Mahmoudinia

Street address

No.162,16th innovation streePardis technology campus, 20 km of Abali road

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1654120596

Phone

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Email

info@sinacellco.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

SinaCell Knowledge-based production Company

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Aniseh Samadi

Position

manager of clinical study unit

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Alireza Firooz
Position
Professor of dermatology
Latest degree
Specialist
Other areas of specialty/work
Dermatology
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Person responsible for updating data

Contact
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Tehran University of Medical Sciences
Full name of responsible person
Maryam Ahmadi
Position
Research Expert
Latest degree
Master
Other areas of specialty/work
Clinical Research
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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
Not applicable
Data Dictionary
Not applicable