Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Nov 2026

Investigating the effectiveness of Alovera spray on diabetic foot ulcers

Protocol summary

Study aim
Determining the effect of ALOVERA spray on the treatment of Diabetic Foot Ulcers

Design
A clinical trial with a control group, with parallel, single-blind, randomized groups, will be conducted on 180 patients with DFUs. Block randomization method and https://www.sealedenvelope.com was used to randomize the samples.

Settings and conduct
180 diabetic patients with DFU are selected with the inclusion criteria and will be randomly divided into 3 groups [Control groups, intervention 1 (silver nanoparticles) and intervention 2 (hypochlorous acid] using the randomized block method. Patients will be followed up and treated during 5 sessions as weekly visits. The reduction of bacterial load and wound surface will be measured at the beginning, second week, and at fifth week.

Participants/Inclusion and exclusion criteria
Patients with neuropathic and neuroischemic diabetic foot ulcers, patients with Pedis grade 1 and 2 diabetic foot ulcers, patients with Wegener grade 1 to 3 diabetic foot ulcers

Intervention groups
Control group: In the weekly visit, the wound will be washed with N/S, then sharp debridement and appropriate dressing will be used. During the week, the patient will wash the wound 3 times and change the dressing. Intervention group 1: In the weekly visit, the wound is washed with N/S and Silvosept spray silver (Chitotech) is used to disinfect the wound, and then sharp debridement and dressing suitable for the patient will be used. Intervention group 2: In the weekly visit, the wound is washed with N/S and ALOVERA spray (Negin Daro Azerbaijan Company) is used to disinfect the wound, and then sharp debridement and then appropriate dressing for the patient will be used. In the intervention groups, the patient will wash, disinfect and change the dressing 3 times in a week. The duration of intervention is 5 weeks.

Main outcome variables
Wound area & bacterial load on the wound surface

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20080904001199N7**
Registration date: **2023-04-30, 1402/02/10**
Registration timing: **prospective**

Last update: **2023-04-30, 1402/02/10**
Update count: **0**

Registration date
2023-04-30, 1402/02/10

Registrant information

Name
Mohammad Reza Amini

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8822 0038

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mramini@tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-22, 1402/03/01

Expected recruitment end date
2024-03-19, 1402/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Investigating the effectiveness of Alovera spray on diabetic foot ulcers

Public title
Investigating the effectiveness of Alovera spray on diabetic foot ulcers

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with diabetic neuropathic and neuroischemic foot ulcers PEDIS Grade 1&2 Diabetic Foot Ulcer Wagner Grade 1, 2 and 3 Diabetic Foot Ulcer

Exclusion criteria:
Getting infected with Covid-19

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size
Target sample size: **180**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients referred to the diabetic foot ulcer clinic after selection based on inclusion and exclusion criteria are divided into three groups control, intervention 1, and intervention 2 using the Block Randomization method and blocks of 6. Using the study randomization available at https://www.sealedenvelope.com/ we will create sequences and blocks of 6 for randomization. Sealed Envelope Ltd. 2022. Create a blocked randomisation list. [Online] Available from: https://www.sealedenvelope.com/simple-randomiser/v1/lists [Accessed 12 Dec 2022].

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, three methods will be used to wash and disinfect the wound surface. After a general explanation to the patients about the method and type of treatment in this plan, the patients will be randomly assigned to treatment groups based on blocks by the principal researcher. The doctor and nurse have no role in choosing the treatment group, but they know which patients are in the intervention group and which are in the control groups. All three groups are given unlabeled sprays. Neither patients nor their families are aware of what type of spray they are using. The results of the study and grouping of patients are recorded as a code, so the data analyst is also unaware of the type of group therapy.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of the Endocrinology and Metabolism Research Institute, Tehran University of Medica

Street address
Endocrinology Research Institute, 5th floor, Dr. Shariati Hospital, North Kargar St., Enghelab Square, Tehran

City
Tehran

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Tehran

Postal code
1411713137

Approval date
2023-03-01, 1401/12/10

Ethics committee reference number
IR.TUMS.EMRI.REC.1401.151

Health conditions studied

1

Description of health condition studied
Diabetic Foot Ulcers

ICD-10 code
E11.4

ICD-10 code description
Type 2 diabetes mellitus with neurological complications

Primary outcomes

1

Description
wound area

Timepoint
Before the intervention - the first week after the intervention - the second week after the intervention - the third week after the intervention - the fourth week after the intervention - the fifth week after the intervention

Method of measurement
Using a ruler and ImageJ software

2

Description
The bacterial load on the wound surface

Timepoint
Before the intervention - the second week after the intervention - the fifth week after the intervention

Method of measurement
Microbial culture will be done using swap and agar medium.

Secondary outcomes

empty

Intervention groups

1

Description
Control group: In these patients, standard treatment (washing with normal saline, debridement and dressing) will be performed. Wound assessment will be done for patients during 5 sessions as weekly visits using the Triangle Wound Assessment tool. In every weekly visit, while washing the wound with normal saline solution and performing sharp debridement, the wound surface is covered with a suitable dressing. Meanwhile, the patient will use normal saline solution every other day during the week when changing the dressing (3 times). In each visit, the wound surface is also measured and recorded. Microbial culture will be done at the beginning of the intervention, the second week and the fifth week. The duration of the intervention is 5 weeks.

Category
Treatment - Drugs

2

Description
Intervention group 1: in these patients, in addition to the standard wound treatment (washing with normal saline, debridement and dressing), the surface of the wound will be disinfected using Silvocept spray with the main composition of silver (Chitotech company). Wound assessment is performed for patients during 5 sessions as a weekly visit using Triangle Wound Assessment tool. At each visit after sharp debridement, the surface of the wound is covered with gauze impregnated with Silvocept for 3-4 minutes and finally the surface of the wound is closed with a suitable dressing. In addition, the patient will use the spray in the same way during the week (3 times) when changing the dressing. At each visit, the wound surface is also measured and recorded. Microbial culture will be done before and after using the spray at the beginning of the intervention, the second week and the fifth week. The duration of the intervention is 5 weeks.

Category
Treatment - Drugs

3

Description
Intervention group 2: in these patients, in addition to the standard wound treatment (washing with normal saline, debridement and dressing), the surface of the wound will be disinfected using ALOVERA spray (Negin Daro Azerbaijan). Wound assessment is performed for patients during 5 sessions as a weekly visit using Triangle Wound Assessment tool. At each visit after debridement, the wound surface is covered with gauze soaked in ALOVERA for 3-4 minutes and finally the wound surface is closed with a suitable dressing. In addition, the patient will use the spray in the same way during the week (3 times) when changing the dressing. At each visit, the wound surface is also measured and recorded. Microbial culture will be done before and after using the spray at the beginning of the intervention, the second week and the fifth week. The duration of the intervention is 5 weeks.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Diabetes Clinic, Diabetes Research Center, Endocrinology and Metabolism Research Institute

Full name of responsible person
Dr Mohammad Reza Mohajeri Tehrani

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Endocrinology Research Institute, 5th floor, Dr. Shariati Hospital, North Kargar St., Enghelab Square, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr. Akbar Fotouhi

Street address
6th floor, Research Deputy, Central Office of TUMS,keshavarz Blvd., Enghelab Square, Tehran

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Tehran University of Medical Sciences

Proportion provided by this source
30

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

2

Sponsor

Name of organization / entity
Negin Daro Azerbaijan CO

Full name of responsible person
Mir Ali Asghar Seyed Hosseini

Street address
4th floor, No. 27, Goya Street, Imam Khomeini Ave.

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Negin Daro Azerbaijan CO

Proportion provided by this source
70

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
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr. Mohammad Reza Amini

Position
Assisstant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Diabetic Foot

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Person responsible for scientific inquiries

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Full Professor

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Diabetic Foot

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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
Due to ethical considerations

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable