

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 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)

##### Phone

+98 21 8822 0038

##### Email address

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

##### Province

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

##### **Street address**

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

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+98 21 8822 0037

##### **Email**

mrmohajeri@tums.ac.ir

## **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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**Postal code**  
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**Email**  
a.hoseini1397@gmail.com  
**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**  
Assistant Professor  
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## **Person responsible for scientific inquiries**

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## Person responsible for updating data

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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