# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 2026

## Investigating the effectiveness of Farmisol spray on diabetic foot ulcers

## Protocol summary

**Study aim**
Determining the effect of Farmisol spray on the treatment of Diabetic Foot Ulcers (DFUs)

**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**
Inclusion criteria: Patients with neuropathic and neuroischemic DFUs, Pedis grade 1 and 2 and Wagner grade 1 and 2 diabetic foot ulcers; Exclusion criteria: Getting infected with covid 19

**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 Formisol spray hypochlorous acid (Arshiya) 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 in all groups is 5 weeks.

**Main outcome variables**
Wound area and wound bacterial load

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20080904001199N6**
Registration date: **2023-02-11, 1401/11/22**
Registration timing: **prospective**

Last update: **2023-02-11, 1401/11/22**
Update count: **0**

**Registration date**
2023-02-11, 1401/11/22

**Registrant information**

**Name**
Mohammad Reza Amini

**Name of organization / entity**

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Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2023-02-20, 1401/12/01

**Expected recruitment end date**
2023-11-21, 1402/08/30

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**

empty

**Scientific title**
Investigating the effectiveness of Farmisol spray on diabetic foot ulcers

**Public title**
Investigating the effectiveness of Farmisol 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 Diabetic Foot Ulcer
**Exclusion criteria:**
Getting infected with Covid-19
**Age**
No age limit
**Gender**
Both

**Phase**
3
**Groups that have been masked**

- 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. Patients will be randomly assigned to treatment groups based on blocks by the main researcher. Doctors and nurses have no role in choosing the treatment group. The results of the study and grouping of patients are recorded as a code, so the data analyst is unaware of the type of 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
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**Postal code**
1411713137
**Approval date**
2022-11-13, 1401/08/22
**Ethics committee reference number**
IR.TUMS.EMRI.REC.1401.046

## 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 Formisol spray containing hypochlorous acid HOCL (Arshiya Gol Darman Company). 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 Formisol 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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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

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**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor**

**organization/entity?**
Yes
**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**
Gol Darman Arshiya Co.
**Full name of responsible person**
Sedigheh Zandipour
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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**
Gol Darman Arshiya Co.
**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**
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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