

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

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

2023-02-20, 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

City

Tehran

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Tehran

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

Street address

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

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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?

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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4th Floor, No. 8, 12th Alley, Mir-Emad St., Motahari St.

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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**

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Amini

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Diabetic Foot PhD

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Mohajeri Tehrani

Position

Full Professor

Latest degree

Subspecialist

Other areas of specialty/work

Endocrinology

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Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

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Assistant Professor

Latest degree

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Other areas of specialty/work

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