

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Evaluation of the effectiveness of Hyiodine comparison standard treatment on healing of Diabetic Foot Ulcer: a randomized single-blind controlled trial

Protocol summary

Study aim

Determining the effectiveness of Hyiodine comparison standard treatment on healing of Diabetic Foot Ulcer

Design

A single-blind, randomized, controlled and parallel-group clinical trial on 96 patients with diabetic foot ulcers.

Block Randomization method is used for randomization

Settings and conduct

96 patients with diabetic foot ulcers who will be included in the study based on the inclusion and exclusion criteria and will be divided into two groups "control, intervention (Hyiodine)" (48 patients in each group). The intervention will last four weeks. Except nurse who will dressing, the executive agents of the study and statistical analysis will not be informed about the code of the random sequence. This study will be conducted in two centers; Diabetes Clinic, Diabetes Research Center in Tehran and diabetic foot clinic in Ahvaz

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with neuropathic and neuroischemic diabetic foot ulcers; PEDIS grade 1 and 2 diabetic foot ulcers; Wegener's grade 1 and 2 diabetic foot ulcers; patients with hemoglobin A1c less than or equal to 8.5 Exclusion criteria: suffering from covid-19, skin allergies, thyroid diseases, coagulation diseases

Intervention groups

Control group (standard treatment including washing with normal saline, debridement and dressing), intervention group (standard treatment with Hyiodine dressing). The duration of intervention in all groups is four weeks.

Main outcome variables

Wound area and bacterial load on the wound surface

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080904001199N8**

Registration date: **2023-08-05, 1402/05/14**

Registration timing: **prospective**

Last update: **2023-12-25, 1402/10/04**

Update count: **1**

Registration date

2023-08-05, 1402/05/14

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

2023-08-23, 1402/06/01

Expected recruitment end date

2024-04-19, 1403/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of Hyiodine comparison

standard treatment on healing of Diabetic Foot Ulcer: a randomized single-blind controlled trial

Public title

Determining the effectiveness of Hyiodine comparison standard treatment on healing of Diabetic Foot Ulcer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with diabetic neuropathic and neuroischemic foot ulcers Patients with PEDIS Grade 1 and 2 Diabetic Foot Ulcer Patients with Wagner Grade 1 and 2 Diabetic Foot Ulcer Patient with the hemoglobin A1c less than and equal to 8.5

Exclusion criteria:

Getting infected with Covid-19 have skin allergies have thyroid disease have coagulation disorders

Age

From **30 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

Diabetic patients with foot ulcers are randomly divided into two groups "control, intervention" after examination and if they meet the criteria to enter the trial. The random block method with blocks of four will be used by using /www.sealedenvelope.com for random allocation. A numerical code is defined for the random sequence, and people receive the numerical code in the same order as they enter and are placed in the corresponding group according to the block.

Blinding (investigator's opinion)

Single blinded

Blinding description

Except nurse who will dressing, the executive agents of the study and statistical analysis will not be informed about the code of the random sequence. In this study, the nurse (or doctor) measuring the size of the wound, the microbiology laboratory staff and the statistical analyzer are unaware of the allocation of patients to the study groups, but the patients cannot be blind due to the difference in the shape of the dressings.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Endocrine & Metabolism Research Institute - Tehran University of Medic

Street address

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

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Province

Tehran

Postal code

1411713137

Approval date

2023-07-15, 1402/04/24

Ethics committee reference number

IR.TUMS.EMRI.REC.1402.038

Health conditions studied

1

Description of health condition studied

Diabetic Foot Ulcers

ICD-10 code

E10.621

ICD-10 code description

Type 1 diabetes mellitus with foot ulcer

2

Description of health condition studied

Diabetic Foot Ulcers

ICD-10 code

E11.621

ICD-10 code description

Type 2 diabetes mellitus with foot ulcer

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

Method of measurement

Using digital calipers and ImageJ software. After washing and debriding the wound to measure the surface of the wound, in addition to photography, a digital caliper is used to calculate the largest length and width of the wound. The depth of the wound is also measured and recorded using a probe

2

Description

The bacterial load on the wound surface

Timepoint

Before the intervention - the second week after the intervention- the fourth week after the intervention

Method of measurement

Microbial culture will be done using swap and agar medium. Bacterial colonies are reported qualitatively and quantitatively

Secondary outcomes

1

Description

Side effects of treatment

Timepoint

throughout the intervention and the fifth week after the intervention

Method of measurement

There will be phone and in-person reviews. Registration is done in the case report form (CRF).

Intervention groups

1

Description

Control group: These patients will receive standard treatment including washing with normal saline, debridement and dressing. Every week, after performing sharp debridement and washing the wound with normal saline solution, the wound surface is appropriately dressed. In addition, the patient changes the dressing every 48 hours during the week (three times a week) using saline solution. At the beginning of the treatment and at the end of each week when the patient visits, the wound surface is measured and recorded. Microbial cultures are performed before the intervention, in the second week and in the fourth week after the intervention. The duration of the intervention is four weeks.

Category

Treatment - Drugs

2

Description

Intervention group: in these patients, in addition to the standard wound treatment (washing with normal saline, debridement and dressing), the wound surface will be disinfected using Hyiodine (Nikan Teb Kimia Company). At each visit after debridement, the wound surface is covered with gauze impregnated with Hyiodine and finally the wound surface is closed with a suitable dressing. Meanwhile, during the week, the patient will use Hyiodine solution every 48 hours (three times a week) when changing the dressing in the same way. At the beginning of the treatment and at the end of each week when the patient visits, the wound surface is

measured and recorded. Microbial cultures are performed before the intervention, in the second week and in the fourth week after the intervention. The duration of the intervention is four 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

Nikan Teb Kimia Company

Full name of responsible person

Mahyar Haj Ali

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Unit 1, 1st Floor, Ibn Sina Building, No. 0, 31st Street, Amaj Street, Youssef Abad

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Web page address

<https://www.nitkaco.com>

Grant name

Grant code / Reference number

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

No

Title of funding source

Nikan Teb Kimia 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
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Position
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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