Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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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
2023-08-23, 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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Tehran
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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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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
Nikan Teb Kimia Company
Full name of responsible person
Mahyar Haj Ali
Street address
Unit 1, 1st Floor, Ibn Sina Building, No. 0, 31st Street, Amaj Street, Youssef Abad
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Phone
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info@nitkaco.com
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

Full name of responsible person

Dr. Mohammad Reza Amini

Position

Assistant Professor

Latest degree

Ph.D.

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