

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

##### City

Tehran

##### 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

##### **Street address**

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

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1411413137

##### **Phone**

+98 21 8822 0037

##### **Email**

mrmohajeri@tums.ac.ir

## **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

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1433863561

##### **Phone**

+98 21 2202 8822

##### **Email**

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  
**Street address**  
Endocrinology Research Institute, 5th floor, Dr.  
Shariati Hospital, North Kargar St., Enghelab Square,  
Tehran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1411413137  
**Phone**  
+98 21 8822 0037  
**Email**  
mramini@tums.ac.ir

## 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  
**Street address**  
Endocrinology Research Institute, 5th floor, Dr.  
Shariati Hospital, North Kargar St., Enghelab Square,

Tehran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1411413137  
**Phone**  
+98 21 8822 0037  
**Email**  
mrmohajeri@tums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Dr. Ozra Tabatabaei-Malazy  
**Position**  
Assistant Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Pharmacology  
**Street address**  
Endocrinology Research Institute, 5th floor, Dr.  
Shariati Hospital, North Kargar St., Enghelab Square,  
Tehran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1411413137  
**Phone**  
+98 21 8822 0037  
**Email**  
tabatabaeiml@sina.tums.ac.ir

## 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