

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 2026

### Evaluation of the effect of the herbal medicine Wound Healer on the healing of diabetic foot ulcers: A randomized double-blind clinical trial

#### Protocol summary

##### Study aim

The effect of Wound Healer on the treatment of neuropathic and neuro-ischemic diabetic wounds in patients with diabetic foot

##### Design

The diabetic patients included in the study ( $n = 80$ ) will be studied as Block Randomization. These groups will be matched for the nature of the wounds, the entry and exit factors, and other influencing factors. Patients will be evaluated weekly by the clinic for discharge, color, and size of the wound, and the results will be recorded in the relevant table. The first and last visit will be done by an endocrinologist or infectious disease specialist and the second, third and fourth visits by the trained person. Medicines will be delivered to patients each week and a blank package will be delivered the following week.

##### Settings and conduct

Diabetes Clinic of Diabetes Research Center

##### Participants/Inclusion and exclusion criteria

Inclusion criteria are: 1. Neuropathic, neuro-ischemic diabetic foot ulcer 2. Have signed informed consent to participate in the study 3. No skin diseases in the foot area 4- Diabetic foot ulcers with grade I, II and III lesions according to Wagner's diagnostic criteria 5. Age less than 70 years. Exclusion criteria are: 1. Pregnancy and lactation 2- Having autoimmune diseases and cancer Brachial leg index lower than 0.7 4- People with HbA1c greater than 8 to 9% (people with uncontrolled blood sugar)

##### Intervention groups

In this study, we aimed to investigate the therapeutic effect of Wound Healer on healing of infectious diabetic foot ulcers. We need two groups for this purpose: 1. People with infectious wounds who receive their usual antibiotic treatment. 2. People with infectious wounds who receive topical Wound Healer in addition to antibiotic treatment for 4 weeks daily.

##### Main outcome variables

1- Shortening the time of wound healing or closing 2-

Symptoms of a wound infection can be resolved 3-  
Reduce the size of the wound by 50%

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20111228008551N3**

Registration date: **2019-11-26, 1398/09/05**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-11-26, 1398/09/05**

Update count: **0**

##### Registration date

2019-11-26, 1398/09/05

##### Registrant information

##### Name

mohamad ansari

##### Name of organization / entity

university medicine

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8899 1593

##### Email address

ansarimo@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-11-05, 1398/08/14

##### Expected recruitment end date

2020-05-05, 1399/02/16

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Evaluation of the effect of the herbal medicine Wound Healer on the healing of diabetic foot ulcers: A randomized double-blind clinical trial

**Public title**  
The effect of Wound Healer on diabetic foot

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
 Neuropathic, neuro-ischemic diabetic foot ulcer Signing informed consent to participate in the study No foot skin disease Diabetic foot patients with ulcer grades 1, 2, and 3 based on Wagner diagnostic criteria Age less than 70 years  
**Exclusion criteria:**  
 Pregnancy and lactation Autoimmune diseases and cancer Ankle-Brachial Index less than 0.7 People with HbA1c greater than 8%

**Age**  
To **70 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

**Sample size**  
Target sample size: **80**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
The sample randomization method will be based on the Block Randomization table. Patients with diabetic foot ulcer are divided into two groups of "control and medication" based on the block randomization table after examination and if they meet the inclusion criteria. The doctor and nurse will not play a role in determining the treatment group.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
Regarding of how the patients are randomly selected and the principal that investigator is separated from the treatment team, physicians and nurse practitioners will not play a role in selecting patients for treatment groups, and patients will be unaware of their treatment grouping.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**  
Patients with diabetic foot ulcer are divided into two groups of "control and medication" based on the block

randomization table after examination and if they meet the inclusion criteria. The doctor and nurse will not play a role in determining the treatment group.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Endocrine & Metabolism Research Institute - Tehran  
University of Medical Science

##### Street address

Diabetes Clinic, Shahrivar St, North kargar Ave.

##### City

Tehran

##### Province

Tehran

##### Postal code

1411413137

#### Approval date

2019-07-17, 1398/04/26

#### Ethics committee reference number

IR.TUMS.EMRI.REC.1398.028

## Health conditions studied

### 1

#### Description of health condition studied

Diabetic patient with infected foot ulcer

#### ICD-10 code

E11.6

#### ICD-10 code description

Type 2 diabetes mellitus with other specified complications

## Primary outcomes

### 1

#### Description

50% reduction in wound size

#### Timepoint

weekly

#### Method of measurement

The size of the wound is measured with a graded ruler and digitally photographed, and finally the image will be analyzed by ImageJ software.

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group: Diabetic patients with infectious wounds who receive topical "Wound Healer" daily in addition to antibiotic treatment for 4 weeks daily.

### Category

Treatment - Drugs

## 2

### Description

Control group: Diabetic patients with infectious wounds, who receive their usual antibiotic treatment.

### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Diabetes Clinic of Diabetes Research Center

#### Full name of responsible person

Dr. Ensieh Nasli

#### Street address

Diabetes Clinic, Shahrivar St, North Kargar Ave.

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#### Phone

+98 21 8833 4195

#### Email

mramini@tums.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Dr. Mohammad Ansari

#### Street address

Medicine Faculty, Keshavarz Bld.

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Tehran

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#### Phone

+98 21 4444 6226

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ansarimo@sina.tums.ac.ir

#### Grant name

#### Grant code / Reference number

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

No

### Title of funding source

Drug Company

### Proportion provided by this source

90

### 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

Persons

## 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

Researcher

#### Latest degree

Medical doctor

#### Other areas of specialty/work

General Practitioner

#### Street address

Shariati Hospital, North Kargar

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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 Ansari

#### Position

Assistant Prof.

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Biochemistry

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Mahsa Pilehvari  
**Position**  
Project Assistant  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Biochemistry  
**Street address**  
No. 35, Aqiqi St, Kerman St, Resalat Hwy.  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available