

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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+98 21 8833 4195

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ansari

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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

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

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Person responsible for scientific inquiries

Contact

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Latest degree

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Biochemistry

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Person responsible for updating data

Contact

Name of organization / entity

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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.

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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