

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Evaluation of Dermaheal Ointment Healing Effects on Diabetic Foot Ulcer: Double-Blind Randomized Clinical Trial Study

Protocol summary

Study aim

Evaluation of Dermaheal Ointment Effects on Foot Ulcers in diabetic patients

Design

In this study, diabetic patients either type 1 or type 2 with a nonhealing wound at the Clinic of Diabetes Research Center, Endocrinology and Metabolism Research, Tehran University of Medical Sciences. Patients are then randomly divided into two groups A and B (Dermahil or Eucerine) using a randomized randomized table. In both groups wound and surrounding tissues will be irrigated by normal sterile saline and then dried with sterile gauze. Wounds will be treated by Placebo or Dermaheal Ointment under A or B Ointments. Ointments should be used for 4 consecutive weeks once a day with changing the dressing. At the end of each week, based on checklists and digital images, the effectiveness of the dermaheal in the treatment of diabetic ulcers will be assessed.

Settings and conduct

Diabetes Clinic - DRC

Participants/Inclusion and exclusion criteria

Study inclusion criteria : 1- Wegener G 1 and 2 diabetic ulcers 2 - 4 weeks old wound in the area of legs and extremities (toes, soles of the feet, heels, on the toes) 3 - Age: 18 to 80 years 4 - Body mass index: 35 -18 5 - Wound area: 1 to 30 square centimeters 6 - $0.7 \leq ABI \leq 1.2$ 7 - Being consciousness at the beginning of the study
Inclusion criteria: 1 - Smoking and drug addiction 2- Taking medications that may interfere with wound healing, such as corticosteroids, immunosuppressive agents, and cytotoxic agents 3 - Simultaneous disease that may have negatively affect wounds healing such as cancer, vasculitis, kidney and liver failure, advanced heart failure

Intervention groups

Placebo group (standard treatment with Eucerin) and treatment group (standard treatment with Dermaheal ointment)

Main outcome variables

Area of ulcer Wound color Wound discharge

General information

Reason for update

Acronym

SDWHE

IRCT registration information

IRCT registration number: **IRCT20080904001199N4**

Registration date: **2020-10-05, 1399/07/14**

Registration timing: **prospective**

Last update: **2020-10-05, 1399/07/14**

Update count: **0**

Registration date

2020-10-05, 1399/07/14

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

2020-10-22, 1399/08/01

Expected recruitment end date

2021-06-21, 1400/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of Dermaheal Ointment Healing Effects on Diabetic Foot Ulcer: Double-Blind Randomized Clinical Trial Study

Public title
Dermaheal Effect on Diabetic Foot Ulcer

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Wagner G 1&2 Diabetic Foot Ulcer Neuropathic and Neuroischemic Ulcer $0.7 \leq \text{ABI} \leq 1.2$
Exclusion criteria:
Patient Disagreement to Participate Use of Medications that can Interfere with Wound Healing such as Corticosteroids, Immunosuppressive agents, and Cytotoxic agents

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
The first step in the random process is to create a random sequence. The second step after creating a random sequence is to hide the generated sequence. To use the random number table, we must first determine the number of the table to read. The second is to consider numbers for different groups (for example, pair numbers for intervention A and individual numbers for intervention B, then hand over one of the numbers and move in one of the directions predetermined and record the numbers We assign to different groups. Blocking is usually used to create a balance in the number of specimens assigned to each of the groups studied, for example, in blocks of 4 that have two allocations to the intervention group and two allocations to the control group is taken.

Blinding (investigator's opinion)
Double blinded

Blinding description
Given the fact that the treatments are prescribed as unprinted tubes, also the appearance of both ointments is similar in both control and intervention groups, the patient will not be informed about her/his assignment to the control or intervention group. Forasmuch as groups

will be marked by letters A and B; and patient assignment to either A or B groups will be done using block randomization, therefore, the treating and wound assessor physician will not be informed of the patient's group assignment when examining the wound using a checklist. This will reduce the observation bias (data collection) which arises from mental presupposition. The second principal researcher will also be unaware of the grouping details. Finally, the statistician will statistically analyze the data without knowing the treatment assigned to group A or B. The First Principal researcher is not blinded and can reopen the codes and be informed about the received treatments of each patient (if necessary or and at the end of the study).

Placebo
Used

Assignment
Parallel

Other design features
No

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Institutional Research committee Endocrine & Metabolism Research Institute - Tehran University of Me

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NO 10, Jalal-AL-Ahmad St., Chmaran HWY., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

14117-13137

Approval date

2020-09-23, 1399/07/02

Ethics committee reference number

IR.TUMS.EMRI.REC.1399.036

Health conditions studied

1

Description of health condition studied

Diabetic Foot Ulcer

ICD-10 code

E11.4

ICD-10 code description

Type 2 diabetes mellitus with neurological complications

Primary outcomes

1

Description

Ulcer Area

Timepoint

End of every week

Method of measurement

Images & and ruler

2

Description

Wound Discharge

Timepoint

End of every week

Method of measurement

Color, odor and amount by wound healing checklist

3

Description

Surrounding tissues

Timepoint

End of every week

Method of measurement

Color, hotness, edema and sense by wound healing checklist

Secondary outcomes

1

Description

ABI

Timepoint

End of treatment

Method of measurement

ABI measurement Device

2

Description

FBS

Timepoint

End of treatment

Method of measurement

Glucometer

3

Description

Pain severity

Timepoint

End of every week

Method of measurement

Visual pain scale

Intervention groups

1

Description

Intervention group: Dermaheal Ointment In the form of

ready-to-use tubes without printing. The wound and surrounding tissues will be cleansed with saline solution and dried with sterile gauze. Then, the dermaheal ointment will be applied to the wound using an abaisse-langue and, fixed by the anti-allergic adhesive & a four-layer sterile dry gauze. Changing the dressing and applying the ointment should be done once a day for 4 weeks. Darmaheal ointment is a dressing based on herbal and natural products including Arnebia euchroma, thymes, Maticaria chamomilla L., Curcuma longa, wax, honey, and olive oil, which is produced by Darudarman Salafchegan Knowledge-Based Co.

Category

Treatment - Drugs

2

Description

Placebo group In the form of ready-to-use tubes without printing. The wound and surrounding tissues will be cleansed with saline solution and dried with sterile gauze. Then, the placebo dressing will be applied to the wound using an abaisse-langue and, fixed by the anti-allergic adhesive & a four-layer sterile dry gauze. Changing the dressing and applying the ointment should be done once a day for 4 weeks. Placebo dressing contains the inert substance Eucerin, which is produced by Darudarman Salafchegan Knowledge-Based Co.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Clinic - DRC

Full name of responsible person

Kamelia Rambod

Street address

North Kargar st., Shahrivar St.

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2222233333

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rambod.camelia@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Darudarman Salafchegan Co. (Knowledge-based)

Full name of responsible person

Ali Shariatmadari

Street address

first floor- No. 66 – Tousi st. – Dr. Gharib st. –
Keshavarz blvd. -Tehran

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1419833371

Phone

+98 21 6690 9061

Email

Ali.sh1345@yahoo.com

Web page address

<https://darudarmanco.com/>

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Darudarman Salafchegan Co. (Knowledge-based)

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**

Endocrinology and Metabolism Research Institute

Full name of responsible person

Mohammad Reza Amini

Position

DF PhD

Latest degree

Ph.D.

Other areas of specialty/work

DF PhD Student

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Dr. Shariati Hospital 5th floor

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Reza Mohajeri Tehrani

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Endocrine

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Person responsible for updating data**Contact****Name of organization / entity**

Center for Knowledge-Based institutions and
companies, Vice-Presidency for Science & Technology

Full name of responsible person

Pouya Salahi

Position

Researcher

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Salahi.p93@gamil.com

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

ethical

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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

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

Title and more details about the data/document

Wound healing checklist, Images, ABI

When the data will become available and for how long
Per 3 month

To whom data/document is available
Dr. Mohammad Reza Amini

Under which criteria data/document could be used
Primary Evaluation of the Process and Under Certain Circumstances

From where data/document is obtainable
Ethics Committee endocrine & Metabolism Research institute - Tehran University of Medical Sciences

What processes are involved for a request to access data/document
Hand over to the Project Executor and he will refer to the Committee of Ethics

Comments