

# 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

##### Street address

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.

#### **City**

Tehran

#### **Province**

Tehran

#### **Postal code**

2222233333

#### **Phone**

+98 21 8822 0037

#### **Email**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

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

**Street address**

Dr. Shariati Hospital 5th floor

**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**

Mohammad Reza Mohajeri Tehrani

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Endocrine

**Street address**

Dr. shariati Hospital

**City**

Tehran

**Province**

Tehran

**Postal code**

1411413137

**Phone**

+98 21 8822 0037

**Email**

mrmohajeri@tums.ac.ir

**Web page address**

<http://emri.tums.ac.ir>

**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

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1419833371

**Phone**

+98 21 8822 0096

**Email**

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**