

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### Effect of Teucrium polium on diabetic foot ulcer

#### Protocol summary

##### Study aim

Determination of therapeutic effect of Teucrium polium extract on healing process of diabetic foot, compared to placebo.

##### Design

Sixty type 1 and type 2 diabetic patients with 1st or 2nd degree foot ulcers in the Wagner scale is selected from diabetic clinic. Patients are randomly divided into two arm parallel groups according to block randomization. This phase 2-3 clinical trial is multi center, double blind and placebo controlled study.

##### Settings and conduct

This study will be carried out in Diabetic Clinic of Emam Reza Hospital in Mashhad University of Medical Sciences. The patients receive twice daily dressings of Teucrium polium or placebo ointment. The medical staff and the patients are not aware of the type of treatment.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: type 1 or 2 diabetic patients with 1st or 2nd degree foot ulcer according to Brachial Ankle Index test; 20 to 60 years old patients; Exclusion criteria: uncontrolled diabetic patients with progressed diabetic foot ulcers; diabetic foot ulcer candidate for amputation; disabled patients; patients with renal failure (creatinine clearance above 2); patients under therapy with glucocorticoids; smoker and addict patients; patients with BMI greater than 25; patients suffering from vascular disorder and chronic diseases.

##### Intervention groups

Teucrium polium group: The patients in this group, in addition to common medications for diabetic foot ulcer healing, receive twice daily dressings of Teucrium polium ointment. Placebo group: The patients in this group, in addition to common medications for diabetic foot ulcer healing, receive twice daily dressings of Placebo ointment.

##### Main outcome variables

Diabetic foot ulcer healing; restoration time; surface temperature around the wound.

#### General information

##### Reason for update

##### Acronym

interventional

##### IRCT registration information

IRCT registration number: **IRCT20170821035817N2**

Registration date: **2018-03-26, 1397/01/06**

Registration timing: **prospective**

Last update: **2018-03-26, 1397/01/06**

Update count: **0**

##### Registration date

2018-03-26, 1397/01/06

##### Registrant information

##### Name

Maryam Yaghoubi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3802 2077

##### Email address

yaghoubim6@mums.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

Mashhad university of medical sciences Research Deputy  
-Research Institute of Medicinal Plants of Alborz  
University

##### Expected recruitment start date

2018-04-21, 1397/02/01

##### Expected recruitment end date

2019-03-05, 1397/12/14

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Effect of Teucrium polium on diabetic foot ulcer

### Public title

Effects of Teucrium polium on diabetic ulcer

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Type 1 or 2 diabetic patients suffering with 1st or 2nd degree foot ulcer 20 to 60 years old patients No vascular diseases No suffering from other chronic diseases

#### Exclusion criteria:

Patients with progressed diabetic foot ulcers Patients with diabetic foot ulcer candidate for amputation Disabled patients Patients with renal failure (creatinine clearance above 2) Patients treated with glucocorticoids Smoker and addict patients Patients with BMI greater than 25

### Age

From **20 years** old to **60 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

### Sample size

Target sample size: **60**

Actual sample size reached: **60**

### Randomization (investigator's opinion)

Randomized

### Randomization description

The enrolled patients were randomly assigned into 2 groups according to randomized block design. To select patients, each of them is given number 1 to 60 (total sample size) according to their referral time. Then patients according to their numbers, randomly receives the ointment A or B. Teucrium polium and placebo ointment are filled in identical tube and labeled as ointment A or ointment B. Only principal investigator knows the content of the ointment labeled A or B.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

On identical tubes containing the Teucrium polium and placebo, the ointment A and ointment B are labeled. Other specifications on the labels are identical. Physician, patient, data collector and analyzer are unaware of the nature and meaning of the letters A and B on the label. Only the principal researcher knows the meaning of the letters A and B on the label.

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences.

##### Street address

Emam Reza hospital, Daneshgah Street,

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9137913316

#### Approval date

2017-07-30, 1396/05/08

#### Ethics committee reference number

IR.MUMS.REC.1396.143

## Health conditions studied

### 1

#### Description of health condition studied

Diabetes

#### ICD-10 code

E10, E11

#### ICD-10 code description

Diabetes mellitus

## Primary outcomes

### 1

#### Description

Healing up of diabetic foot ulcer

#### Timepoint

1 month

#### Method of measurement

Ulcer digital photography; microbial ulcer tissue culture

## Secondary outcomes

### 1

#### Description

Ulcer temperature

#### Timepoint

1 month

#### Method of measurement

Digital thermometer

## Intervention groups

### 1

#### Description

Intervention : Teucrium polium ointment dressing apply on ulcer two times a day

#### Category

Treatment - Drugs

### 2

#### Description

Control: Placebo ointment dressing apply on ulcer two times a day

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Emam Reza Hospital diabetic clinic

##### Full name of responsible person

Shapoor Badiie Aval

##### Street address

Masshad, Emam Reza Square, Emam Reza hospital  
Specialist Clinics

##### City

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##### Province

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### 2

#### Recruitment center

##### Name of recruitment center

Institute of Medicinal Plant

##### Full name of responsible person

Hasan Fallah Huseini

##### Street address

Kraj Qazvain Highway, Supa Boulverd, Kavosh  
Boulverd, Jihad-e-Danesgahi Research Complex

##### City

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##### Province

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1345326022

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huseini\_fallah@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Research Deputy

##### Street address

Daneshgah Street, Ghoreishi building, Research  
Deputy

##### City

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##### Grant name

951508

##### Grant code / Reference number

951508

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

Yes

##### Title of funding source

Mashhad University of Medical Sciences

##### Proportion provided by this source

50

##### Public or private sector

Public

##### Domestic or foreign origin

Domestic

##### Category of foreign source of funding

*empty*

##### Country of origin

##### Type of organization providing the funding

Academic

### 2

#### Sponsor

##### Name of organization / entity

Institute of Medicinal plant

##### Full name of responsible person

Research Deputy

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Kavosh Bulverde, Supa Bulverde, 55th km of Tehran-  
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**Grant code / Reference number**  
23453/33  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Institute of Medicinal plant  
**Proportion provided by this source**  
50  
**Public or private sector**  
Public  
**Domestic or foreign origin**  
Domestic  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
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## Person responsible for general inquiries

**Contact**  
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Institute of medicinal plant  
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Hasan fallah huseini  
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## Person responsible for updating data

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## **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