

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)

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+98 51 3802 2077

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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
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2

Recruitment center

Name of recruitment center

Institute of Medicinal Plant

Full name of responsible person

Hasan Fallah Huseini

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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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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Grant name
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
Academic

Person responsible for general inquiries

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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