

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Compare the effects of oral propolis with topical propolis on diabetic foot ulcer

Protocol summary

Study aim

Determination and comparison of the effects of oral and topical propolis on the area of foot ulcer, leukocyte count, pathogenic bacteria, total antioxidant capacity and malondialdehyde

Design

In this trial, 80 patients with diabetic foot ulcers with Grade 1 and 2, which are based on the University of Texas Foot Wound Classification System, are only being studied for standard and common treatment. Qualified individuals will be randomly assigned to four groups using the random numbers table.

Settings and conduct

This study is a clinical trial. In this trial, diabetic patients with diabetic foot ulcers referred to Shahid Beheshti Clinic of Qom University of Medical Sciences are enrolled. Then, 80 patients were randomly assigned to four intervention and control groups.

Participants/Inclusion and exclusion criteria

Diabetic people with foot ulcer

Intervention groups

First intervention group: Three capsules of 500 mg of propolis (daily), Second intervention group: Propolis ointment (1.5 g daily), Third intervention group: Propolis (1500 mg daily) and propolis Ointment (1.5 g daily), Control group: Regular foot wound treatment includes washing with serum physiology

Main outcome variables

Area of foot ulcer, leukocyte count, pathogenic bacteria

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2017040419669N3**

Registration date: **2017-04-15, 1396/01/26**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-02, 1397/02/12**

Update count: **1**

Registration date

2017-04-15, 1396/01/26

Registrant information

Name

Hossein Khadem Haghighian

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Qazvin University of Medical Sciences

Expected recruitment start date

2017-04-04, 1396/01/15

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the effects of oral propolis with topical propolis on diabetic foot ulcer

Public title

Effects of propolis on diabetic foot ulcer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with diabetic foot ulcers grade 1 and 2
Willingness to cooperate

Exclusion criteria:

Patients with wounds functions deep grade and step higher than 1 and 2 Sensitivity to topical formulation

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qazvin University of Medical Sciences

Street address

Qazvin University of Medical Science, Shahid Bahonar Blvd, Qazvin

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Postal code

34197-59811

Approval date

2017-02-27, 1395/12/09

Ethics committee reference number

IR.QUMS.REC.1395.294

Health conditions studied

1

Description of health condition studied

Diabetic food ulcers

ICD-10 code

L97

ICD-10 code description

Ulcer of lower limb, not elsewhere classified

Primary outcomes

1

Description

Area of diabetic foot ulcers

Timepoint

The beginning and End of the study

Method of measurement

With AutoCAD software

2

Description

Average leukocytes in diabetic foot ulcers

Timepoint

The beginning and End of the study

Method of measurement

The sampling

3

Description

The number of pathogenic bacteria

Timepoint

The beginning and End of the study

Method of measurement

The Sampling and culture

4

Description

Total Antioxidant Capacity

Timepoint

The beginning and End of the study

Method of measurement

Eliza kit

5

Description

serum Malondialdehyde

Timepoint

The beginning and End of the study

Method of measurement

Eliza kit

Secondary outcomes

empty

Intervention groups

1

Description

Control group : Rinse with saline daily

Category

Treatment - Drugs

2**Description**

Intervention group 3: 1500 mg Propolis ointment for topical use on the ulcer and 1500 mg Propolis capsules (three 500 mg capsules), daily for 4 weeks.

Category

Treatment - Drugs

3**Description**

Intervention group 2: 1500 mg Propolis ointment for topical use on the ulcer, daily for 4 weeks.

Category

Treatment - Drugs

4**Description**

Intervention group 1: Propolis capsules, 1500 mg(three 500 mg capsules), daily for 4 weeks.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Metabolism and Endocrinology clinic martyr Beheshti Hospital in Qom

Full name of responsible person

Dr. Hossein Khadem Haghighian

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Qazvin University of Medical Sciences

Full name of responsible person

Dr. Taghi Naserpour

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

Yes

Title of funding source

Vice chancellor for research, Qazvin University of Medical Sciences

Proportion provided by this source

100

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**Contact****Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Hossein Khadem Haghighian

Position

Ph.D in Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data on primary and secondary outcomes will be published.

When the data will become available and for how long

After completing the study and analyzing the data

To whom data/document is available

All researchers

Under which criteria data/document could be used

There is no objection to the use of data provided the source of the resource.

From where data/document is obtainable

IRCT site

What processes are involved for a request to access data/document

There is no objection to the use of data provided the source of the resource.

Comments

Person responsible for updating data

Contact

Name of organization / entity

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Assistant Professor

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