Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 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

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Iran (Islamic Republic of)

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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

City

Qazvin

Province

Qazvin

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

śerum 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
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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
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Position
Ph.D in 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