Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Honey and Propolis Lotion on Healing of the Diabetic Foot Ulcers

Protocol summary

Study aim
Determining The effect of Propolis and Honey Lotion on Healing of Diabetic Foot Ulcers

Design
The clinical trial included a control and intervention group selected as a quadruple randomized block with a sample size of 60

Settings and conduct
The present clinical trial study will be performed on diabetic foot ulcer patients referred to the Tehran University Jihad Wound Center with the aim of determining the effect of propolis and honey lotion on healing of diabetic foot ulcer. This study was performed on patients with diabetic foot ulcer and Wagner 1 and 2 neuropathy. The face was chronically treated using digital caliper and BIM software to measure the extent and depth of the wound and after debridement and washing in both test and control groups, in the test group containing propolis and honey in the dressing group. The wound will be placed within one to four weeks depending on the size and size of the wound

Participants/Inclusion and exclusion criteria
Inclusion criteria: A1C Hemoglobin Level Should Not Exceed 8. Insensitivity to Propolis and Honey. Type 1 and Type 2 Diabetes. Neuropathic Wounds of Diabetic Foot Wagner I and II Be over 18 Years of Age. 4 Weeks Or More Has Elapsed Since The Injury. Exclusion criteria: Osteomyelitis Active infection Drug addiction

Intervention groups
The Wound In Both Groups Is Completely Defrozen Prior To Dressing With no Infections. The Control Group After Regular Debridement And wound Washing with Water, Became Regular Dressing. In the Test Group, The Lotion Containing Propolis and Honey will be Dressed on the wound. Propolis and Honey are Sterilized from Tehran University of Medical Sciences Jihad to Effectively Release Prophylactic Materials. That are Solubilized In Accordance with The Institute's Guidelines and Articles on the Proportion of Ethyl Alcohol. in honey.

Main outcome variables
Wound healing

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200113046120N1**
Registration date: **2020-03-02, 1398/12/12**
Registration timing: **retrospective**

Last update: **2020-03-02, 1398/12/12**
Update count: **0**

Registration date
2020-03-02, 1398/12/12

Registrant information
Name
Elham Rasoulian
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-08-23, 1398/06/01
Expected recruitment end date
2019-12-21, 1398/09/30
Actual recruitment start date
2019-09-11, 1398/06/20
Actual recruitment end date
2020-01-30, 1398/11/10

Trial completion date
2020-01-30, 1398/11/10

Scientific title
The Effect of Honey and Propolis Lotion on Healing of the Diabetic Foot Ulcers

Public title
The Effect of Honey and Propolis Lotion on Healing of the Diabetic Foot Ulcers

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with type 1 and type 2 diabetes. The presence of clear neuropathy in the lower limbs Be over 18 years of age It Takes Four Weeks Or More For The Wound To Develop A1C hemoglobin Level Should Not Exceed 8. No SensitivityTo Propolis and Honey Patients with Wagner I and II Diabetic Foot Neuropathic Ulcer (Without Osteomyelitis Or Gangrene) in Areas of Pressure (Plantar Foot Surface

Exclusion criteria:
Osteomyelitis or the presence of congeners in the lower extremities Drug addiction Active wound infection

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**
Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The volume of the blocks was four, giving each block a number Samples were randomly divided into four groups B, B, A, and A Randomly assigned. The volume of the block is quadruple and each block is assigned a number. AABB (1), ABAB (2), ABBA (3), BBAA (4), BABA (5 BAAB (6), The numbers are randomly selected from 1 to 6 and the treatment allocation list is specified as such. A-A-B-B-B-A-A-A-B-A-B-B-A-B-A.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address
No. 17, Enslave Street, South Palestine Street, Nazari Street

City
Tehran

Province
Tehran

Postal code
8915813127

Approval date
2019-04-15, 1398/01/26

Ethics committee reference number
IR.SBMU.PHARMACY.REC.1398.031

Health conditions studied

1

Description of health condition studied
Diabetic Foot Ulcer

ICD-10 code
E08.621

ICD-10 code description
Diabetes mellitus due to underlying condition with foot ulcer

Primary outcomes

1

Description
Diabetic Foot Ulcerf

Timepoint
Evaluation of lotion containing propolis and honey in wound dressing according to the extent and size of the wound for one to four weeks

Method of measurement
Diabetic foot ulcer healing using digital caliper and BIM software

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients with Diabetic Foot Ulcers of Wagner 1 and 2 Neuropathies are Chronic. Propolis and Honey Lotion in This Study, packs in 25 cc Sterile Volume and Prepared From the BiotrapimericAcademicJihad Wound The wound heals within One to Four weeks,

Depending on The Extent and Size of the Wound.

Category

Treatment - Other

2

Description

Control group: Diabetic foot ulcers are treated with Wegner 1 and 2 with simple dressing and received standard treatment.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran University Jihad Wound Center

Full name of responsible person

Elham Rasoulian

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No. 17, Enlargement Street, South Palestine Street, Nazari Street.,Tehran Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarqi

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Grant name

Grant code / Reference number

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

No

Title of funding source

Shahid Beheshti University of Medical Sciences

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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Elham.rasoulian

Position

Student

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for updating data

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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

Yes - There is 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

Yes - There is 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

Evaluation of propolis and honey lotion on diabetic foot ulcer

When the data will become available and for how long

6 month

To whom data/document is available

Comparison of mean changes of foot ulcer area in diabetic foot ulcer patients

Under which criteria data/document could be used

Wagner Diabetic Foot Wound Area 1 and 2

From where data/document is obtainable

University of Tehran of Jahad Ulcer

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

Statistical analysis using spss software

Comments

Accelerate wound healing