

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the Effect of Dressing with Manuka honey and Ordinary dressing on the process of repairing diabetic foot ulcers

Protocol summary

Study aim

Comparison of the effect of dressing with manuka honey and ordinary dressing on the process of repairing diabetic foot ulcers

Design

The trial has a control group, with parallel groups, one blind, non-random allocation, and a sample size of 40 people.

Settings and conduct

The present study will be conducted in Vasei Hospital in Sabzevar. Participants in the study and all medical personnel working in the department will not know the type of groups and the allocation of samples.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Age 40 to 80 years. 2. Type 2 diabetes. 3. Blood sugar between 150-400. Non-Inclusion criteria: 1. No patient consent to participate in the study. 2. A history of high blood sugar of 400 mg. 3. Having various chronic diseases. 4. Need to scrape into debridement. 5. History of addiction use. 6. Mental disability.

Intervention groups

In the intervention group, dressing will be done with Manuka honey and in the usual dressing control group.

Main outcome variables

Diabetic foot ulcer examination.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171219037967N2**

Registration date: **2019-09-13, 1398/06/22**

Registration timing: **retrospective**

Last update: **2019-09-13, 1398/06/22**

Update count: **0**

Registration date

2019-09-13, 1398/06/22

Registrant information

Name

Mehdi Jamalnik

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4441 5745

Email address

mhd.niki67@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-04, 1398/01/15

Expected recruitment end date

2019-06-20, 1398/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Dressing with Manuka honey and Ordinary dressing on the process of repairing diabetic foot ulcers

Public title

Comparison of the effect of Manuka honey and ordinary dressings on diabetic foot ulcers

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients between the ages of 40 and 80 years

hospitalized. Having Type 2 Diabetes Based on Patient Medical Record and Certified Physician. The blood glucose level is between 150-400.

Exclusion criteria:
 Patient dissatisfaction with participation in the study.
 Having a history of high blood sugar of 400 mg over a period of 6 months to one year. Having multiple chronic illnesses. Need to wound debridement. having drug addiction Mental disability

Age
 From **40 years** old to **80 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
 Target sample size: **40**

Randomization (investigator's opinion)
 Not randomized

Randomization description

Blinding (investigator's opinion)
 Single blinded

Blinding description
 Assignment of samples will be randomly divided into two groups of intervention and control, and the participants in the study, as well as the health care staff present in the department (all doctors and nurses) will never know how to assign samples and research groups.

Placebo
 Not used

Assignment
 Parallel

Other design features

Secondary Ids
 empty

Ethics committees

1

Ethics committee

Name of ethics committee
 Ethics committee of Sabzevar University of Medical Sciences

Street address
 Nuclear Martyrs Boulevard, Campus of Sabzevar University of Medical Sciences

City
 Sabzevar

Province
 Razavi Khorasan

Postal code
 9613873136

Approval date
 2019-03-16, 1397/12/25

Ethics committee reference number
 233445555

Health conditions studied

1

Description of health condition studied
 Diabetic foot ulcer

ICD-10 code
 E11.4

ICD-10 code description
 Type 2 diabetes mellitus with neurological complications

Primary outcomes

1

Description
 Assessment and management of foot ulcers in diabetic patients

Timepoint
 Every day for one month

Method of measurement
 Detailed daily examination of the wound by an infectious disease specialist

Secondary outcomes
 empty

Intervention groups

1

Description
 Control group: Normal and routine wound dressing.

Category
 Treatment - Other

2

Description
 Intervention group: dressing for Diabetic foot ulcer with manuka honey 100% ointment prepared from Iran Pharmis Company.

Category
 Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
 Vasei Hospital in Sabzevar

Full name of responsible person
 Mehdi Jamali Nik

Street address
 No. 36, Hekmat 2 Alley, Hekmat Ave, Block 6, Tohid Town.

City

Sabzevar
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Razavi Khorasan
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9617973577
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+98 51 4441 5745
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mhd.niki67@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Deputy of Research and Technology of Sabzevar
University of Medical Sciences
Street address
Nuclear Martyrs Boulevard, Campus of Sabzevar
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Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sabzevar 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
Sabzevar University of Medical Sciences
Full name of responsible person
Mehdi jamali Nik
Position

Faculty Member of School of Nursing
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
No. 36, Hekmat Alley 2, Hekmat Ave, Block 6, Towhid
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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

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

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Participants data file: Information and general results of the data will be publicly available after the research is completed.

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

It will be available For researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Only allowed to know the overall results of the study.

From where data/document is obtainable

For correspondence, please email the author.

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

Approximately 1 month after confirmation of correspondence from the author of the research.

Comments