

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 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 Jamalinik

###### 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**

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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  
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Nuclear Martyrs Boulevard, Campus of Sabzevar  
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mhd.niki67@yahoo.com  
**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  
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No. 36, Hekmat Alley 2, Hekmat Ave, Block 6, Towhid  
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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

#### Contact

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**Full name of responsible person**  
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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**