

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### Comparison between the effect of ozone therapy and honey therapy on diabetic foot ulcers

#### Protocol summary

##### Study aim

This study is a parallel clinical trial with the aim of evaluating honey and ozone therapy on diabetic foot ulcers.

##### Design

A sample of 70 patients with diabetic patients admitted to the hospital in Kermanshah city. In this research, a random allocation method is used. People undergoing omental and curative therapy. In the group of honey therapy, 35 people will be replaced every 3-7 days of dressing and will continue for up to 4 weeks. In the ozone therapy group, 35 patients will be treated using topical ozone gas and intravenous injection Patients are used. Wound healing is based on the PEDIS table and the method of measuring the wound is using a graded ruler. In the course of the study, the wound is measured and recorded. At the end of the wound, each wound is compared with each other.

##### Settings and conduct

This study, which is a sucrose study, is carried out at Bistoon Hospital in Kermanshah. First, 70 nephrologists were studied and randomly divided into two groups of 35 and interventions were performed

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Diabetic patients have grade 3 or 4 renal insufficiency. 2. Patients should be admitted to Bisotun Hospital. 3. Patients between 20-75 years of age. 4. Patients undergo routine treatment Exit criteria: 1. Patients who receive another treatment at the same time. 2. Patients who did not complete the treatment period and were not regular. 3. Patients whose feet require surgical debridement. 4. Patients who die during the study. 5. Patients who are not satisfied with the continuation of treatment. 6. There is a history of deep vein thrombosis 7. There is a history of hemorrhage from the foot

##### Intervention groups

The study is divided into two intervention groups of ozone and honey therapy. After the selection,

participants are placed in one of the two groups: Patients who have received routine treatment in the honey therapy group. After wounding with normal saline, the honey dressing manufactured by HydroTac, Germany, wound on the wound, the size of the dressing depends on the size of the wound. This dressing is carried out 3-7 days once and forty-four weeks, which is first taught by the researcher, and other necessary arrangements will be made by the client or his family. Patients in the ozone therapy group receiving routine treatment, after ozone wound healing with normal saline, an ozonotherapy is performed, 8 times for each patient for 8 weeks of ozone therapy.

##### Main outcome variables

Diabetic foot ulcer : Every 3 to 7 days, once a week, 4 weeks in the honey therapy group & 2 times a week for 4 weeks in the ozone therapy group.

#### General information

##### Reason for update

##### Acronym

KMC

##### IRCT registration information

IRCT registration number: **IRCT20130317012830N32**

Registration date: **2018-02-28, 1396/12/09**

Registration timing: **retrospective**

Last update: **2018-02-28, 1396/12/09**

Update count: **0**

##### Registration date

2018-02-28, 1396/12/09

##### Registrant information

##### Name

Faezeh Jahanpour

##### Name of organization / entity

Bushehr University of Medical Sciences

##### Country

Iran (Islamic Republic of)

**Phone**  
+98 77 1455 0187

**Email address**  
f.jahanpour@bpums.ac.ir

**Recruitment status**  
**Recruitment complete**

**Funding source**  
Bushehr University of Medical Science

**Expected recruitment start date**  
2017-10-23, 1396/08/01

**Expected recruitment end date**  
2018-01-21, 1396/11/01

**Actual recruitment start date**  
empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Comparison between the effect of ozone therapy and honey therapy on diabetic foot ulcers

**Public title**  
Comparison of ozone therapy and honey therapy on diabetic foot ulcers

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Inclusion criteria: 1.diabetic foot ulcers graid 3-4. 2.Patients admitted in the internal ward. 3.Patients aged 20-75 years old. 4.Patients undergo routine treatment.  
**Exclusion criteria:**  
Exclusion criteria: 1.Patients who receive another treatment at the same time. 2.Patients who did not complete the course of treatment and were not regular. 3.Patients who require surgical debridement . 4.Patients who die during the study. 5.Patients who are not satisfied with the continuation of treatment. 6.The history of deep vein thrombosis. 7.There is a history of hemorrhage from the foot ulcer.

**Age**  
From **20 years** old to **75 years** old

**Gender**  
Both

**Phase**  
2

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **70**

**Randomization (investigator's opinion)**  
Not randomized

**Randomization description**  
This research is a randomized clinical trial. The study population was selected from patients with type 2 diabetes mellitus in the Bistoon Hospital of Kermanshah. At first, 70 individuals with diabetes who referred to the internal ward of the hospital were selected and then

randomly assigned patients Random numbers generated by Excel are assigned to two groups of honey and ozonotherapy

**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**  
Vice Chancellor for Research Ethics Committee, Bushehr University of Medical Sciences

**Street address**  
University of medical sciences, Salman farsy, Bushehr

**City**  
Bushehr

**Province**  
Boushehr

**Postal code**  
7514633341

**Approval date**  
2017-09-30, 1396/07/08

**Ethics committee reference number**  
IR.BPUMS.REC.1396.95

**Health conditions studied**

**1**

**Description of health condition studied**  
Diabetes

**ICD-10 code**  
E08

**ICD-10 code description**  
Diabetes mellitus due to underlying condition

**Primary outcomes**

**1**

**Description**  
Diabetic foot ulcer

**Timepoint**  
Every 3 to 7 days, once a week, 4 weeks in the honey therapy group, 2 times a week for 4 weeks in the ozone therapy group

**Method of measurement**  
Determine the wound gradient based on the PEDIS table and measure the wound using a graded ruler

## Secondary outcomes

empty

## Intervention groups

1

### Description

Ozone therapy group: In this group, patients receive a single intravenous line after receiving routine therapies and 50 cc of blood is taken from the patient and combined with 50 cc of ozone for 3 to 4 minutes, and then using an ozone bag that is used on

### Category

Other

2

### Description

Honey Therapy Group: Patients in this group after receiving routine treatments of honey dressing, HydroTac Company, Germany, has been wounded for 3 to 4 days for 4 weeks, and every time a wound is measured.

### Category

Other

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Bisotun Hospital, Kermanshah, Interior

#### Full name of responsible person

Negin Miri

#### Street address

Kermanshah, Allahieh Town, Blvd. Shahed, Molavi Street

#### City

Kermanshah

#### Province

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#### Postal code

6719944436

#### Phone

+98 83 4222 2427

#### Email

MIRI.NEGIN@GMAIL.COM

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Research Deputy of Bushehr University of Medical Sciences

#### Full name of responsible person

Afshin Ostovar

#### Street address

Bushehr University of Medical Sciences

#### City

Bushehr

#### Province

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#### Phone

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#### Email

F-jahanpour@yahoo.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Research Deputy of Bushehr 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

Bushehr University Of Medical Sciences

#### Full name of responsible person

Faezeh Jahanpour

#### Position

PhD in Nursing / Chief Faculty of Nursing

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Nursery

#### Street address

Faculty of Nursing and Midwifery, Bushehr University of Medical Sciences, Bushehr

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Position**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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**

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**

After the end of the study, I will put the myototon in a transparent form for the attendant to the Bushehr University of Medical Sciences

**When the data will become available and for how long**

After the end of the study in early spring 97

**To whom data/document is available**

Bushehr University of Medical Sciences

**Under which criteria data/document could be used**

For diabetic patients, there is a risk of hip amputation and those who have wound healing, in particular after healing after using one of these methods

**From where data/document is obtainable**

negin miri

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

The application must be submitted in writing to the Bushehr University of Medical Sciences

**Comments**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Boushehr University of Medical Sciences

**Full name of responsible person**

Faezeh Jahanpour

**Position**

University professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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Bushehr, Sabzabad, Medical University

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