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)

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Deputy of Bushehr 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
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
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Faezeh Jahanpour
Position
PhD in Nursing / Chief Faculty of Nursing
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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