Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Comparative study on the effect of ozone therapy, honey dressing and combination of ozone and honey dressing on healing of diabetic foot ulcer

Protocol summary

Study aim
The aim of the study is to determine the effect of ozone therapy, honey dressing and combination of ozone and honey dressing on healing of diabetic foot ulcer

Design
A clinical trial with a community-based, practice-oriented control group, with parallel groups, not blinding. Randomized random block method

Settings and conduct
The research sample size consists of 140 patients with diabetic foot(intervention group 105, control group 35) in Imam Reza hospital in Kermanshah city in 2017-2019

Participants/Inclusion and exclusion criteria
The inclusion criteria: Physician and patient satisfaction Age over 18 Do not use corticosteroid during the past month Do not use immunosuppressive drugs Lack of osteomyelitis Lack of smoking Insensitivity to honey and ozone therapy exclusion criteria: unwillingness to cooperate Unwillingness to co-operate with a patient or physician Severe infection (Grade 4 system of the podium) Prescription Drugs Suppressing the Immune System and Corticosteroids Amputation Death

Intervention groups
The intervention in this study is using the 405 honey(The brand of this dress is Made Honey, produced by the Austrian Hartmann Company), Ozone therapy with a Mead device, (produced by Germany). there is no intervention in the control group. The wound examination is performed by Beta Johnson, Padis and Wagner systems, one week after starting treatment, two weeks after starting treatment and at the end of the study.

Main outcome variables
healing of diabetic foot ulcer

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181105041563N3**
Registration date: **2018-12-18, 1397/09/27**
Registration timing: **prospective**

Last update: **2018-12-18, 1397/09/27**
Update count: **0**

Registration date
2018-12-18, 1397/09/27

Registrant information

Name
Somayeh Mahdavikian

Name of organization / entity

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Iran (Islamic Republic of)

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+98 83 3827 9394

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-02-04, 1397/11/15

Expected recruitment end date
2020-02-20, 1398/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative study on the effect of ozone therapy, honey dressing and combination of ozone and honey dressing on healing of diabetic foot ulcer

Public title
Comparative study on the effect of ozone therapy, honey dressing and combination of ozone and honey dressing on healing of diabetic foot ulcer

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Physician and patient satisfaction Age over 18 Do not use corticosteroid during the past month Do not use immunosuppressive drugs Lack of osteomyelitis Lack of smoking Insensitivity to honey and ozone therapy

Exclusion criteria:
Unwillingness to co-operate with a patient or physician Severe infection (Grade 4 system of the podium) Prescription Drugs Suppressing the Immune System and Corticosteroids Amputation Death

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **140**

Randomization (investigator's opinion)
Randomized

Randomization description
Qualified samples were entered into the study by accessible method and randomly divided into intervention groups (Honey, Ozone and Honey-ozone) and control. Blocks were done as follows: To dressing groups with Honey, Ozone and Honey-ozone was assigned A ، B and C codes respectively, and the control group received D code. The study blocks were ABCD, ABDC, ACBD, ACDB, ADBC, ADCB, and the ABCD block was selected as the first block. Patients were assigned to Honey,ozone ,Honey-ozone, and control groups, respectively, and this method continued until the samples were completed.

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
Ethics committee of Kermanshah University of Medical Sciences

Street address
Kermanshah University of Medical Sciences, Shahid Beheshty Blv, Kermanshah University of Medical Sciences, Kermanshah, Iran

City
Kermanshah

Province
Kermanshah

Postal code
6715986479

Approval date
2018-08-14, 1397/05/23

Ethics committee reference number
IR.KUMS.REC.1397.496

Health conditions studied

1

Description of health condition studied
Diabetic foot ulcer

ICD-10 code
E10-E14

ICD-10 code description
Diabetes mellitus

Primary outcomes

1

Description
healing of diabetic foot ulcer

Timepoint
One week after starting treatment, two weeks after starting treatment and at the end of the study

Method of measurement
Wagner ,pedis and beta johnson scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Group 1: Wound, dressed daily, up to 8 weeks, with 405 honey. The brand of this dress is Mede Honey, produced by the Austrian Hartmann Company, wound healing by Beta Johnson, Padis and Wagner systems, one week after starting treatment, two weeks after starting treatment and at the end of the study.

Category

Treatment - Other

2

Description
Intervention group: Group Two: Ozone therapy will be performed in eight weeks (16 times) with a Mead device, produced by Germany. Wound examination by Beta Johnson, Padis and Wagner systems, one week after starting treatment, two weeks after Start treatment and at the end of the study.
Category
Treatment - Other

3

Description
Intervention group: Group 3: In addition to ozone therapy, honey dressing will also be done for 8 weeks. The wound examination is performed by Beta Johnson, Padis and Wagner systems, one week after starting treatment, two weeks after starting treatment and at the end of the study.
Category
Treatment - Other

4

Description
Group 4: In the control group, only routine treatments will be performed. Includes daily washing, debridement, gas dressing and antibiotic therapy (based on prescribing physician). The wound examination is performed by Beta Johnson, Padis and Wagner systems, one week after starting treatment, two weeks after starting treatment and at the end of the study.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Somayeh Mahdavikian
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kermanshah University of Medical Sciences
Full name of responsible person
Behrooz Hamzeh
Street address
address Vice chancellor for research, Kermanshah University of Medical Sciences, Shahid Beheshty Blv., Kermanshah, Iran
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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
Vice chancellor for research, Kermanshah 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
Kermanshah School of Nursing and Midwifery
Full name of responsible person
Somayeh Mahdavikian
Position
Faculty Member
Latest degree
Master
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Nursery
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable