

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 Mahdavian

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 83 3827 9394

Email address

somayeh.mahdavian@kums.ac.ir

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 Mahdavian

Street address

Imam Reza hospital, Baghe abrisham

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Email

Somayeh.Mahdavian@kums.ac.ir

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 Mahdavian

Position

Faculty Member

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Nursing Department, Kermanshah School of Nursing and Midwifery, Ashayer Blv., Kermanshah, Iran

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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

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