Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of topical olive oil on the healing of diabetic foot ulcer in type 2 diabetic patients referred to Bandar Abbas diabetes clinic in 2017

Protocol summary

Study aim

The aim of this study was to investigate the effect of topical olive oil on the improvement of Diabetic Foot Ulcer

Design

Thirty patients were randomly assigned to the intervention group and, in addition to the usual care, topically applied olive oil dressing on their wounds. While patients in the control group (30) were only under normal care with normal saline and dressing.

Settings and conduct

The intervention was performed once a day for 4 weeks in both groups and at the end of each week the ulcer was evaluated

Participants/Inclusion and exclusion criteria

Entry requirements: Patients aged 30-65 years with grade 1 or 2 diabetic ulcers according to Wegener's classification. Having a single ulcer in the legs and extremities (fingers, sole, heel, toe) that lasts at least 4 weeks Creating it past; having a BMI of 35-18; non-smoking, alcohol and drug addiction; not taking drugs that may interfere with wound healing, such as corticosteroids, immunosuppressive agents, and cytotoxic agents; lack of disease At the same time it can cause problems in wound healing, such as cancers, vasculitis, kidney and liver failure, and heart failure. Exclusion criteria: Existing acute ulcer need to receive intravenous antibiotics or gangrene requiring amputation; evidence of wounds Intravenous, ischemic, neurotrophic and traumatic in the patient; absence of referral to the center for tracking and changing dressings in more than two occasions.

Intervention groups

Patients in intervention group: received standard care and daily dressing with sterile gauze and topical olive for 4 weeks. Patients in control group received standard care and daily dressing with sterile gauze at the same time.

Main outcome variables

Wound parameters, including color, drainage, size, total status based on calculated score,fasting plasma sugar, glycosylated hemoglobin will be measured for all patients.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150607022585N4**
Registration date: **2018-12-05, 1397/09/14**
Registration timing: **retrospective**

Last update: **2018-12-05, 1397/09/14**
Update count: **0**

Registration date

2018-12-05, 1397/09/14

Registrant information

Name

Masoumeh Kheirandish

Name of organization / entity

Hormozgan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Hormozgan university of medical scinences

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-08-22, 1396/05/31

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of topical olive oil on the healing of diabetic foot ulcer in type 2 diabetic patients referred to Bandar Abbas diabetes clinic in 2017

Public title
The effect of topical olive oil on the healing of diabetic foot ulcer
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged 30-65 years with grade 1 or 2 diabetic wounds based on Wegener's classification having single ulcers in the legs and extremities (fingers, toes, heels, toes) that develop at least 4 weeks It's past having a BMI of 35- 18 not smoking; alcohol; and drug addiction not taking drugs that may interfere with wound healing, such as corticosteroids, immunosuppressive factors, and cytotoxic agents lack of syncope that may occur in Wound healing can cause problems, such as cancers, vasculitis, kidney and liver failure, and heart failure
Exclusion criteria:
Existing anesthetized wounds requiring intravenous antibiotics or gangrene requiring amputation evidence of intravenous, ischemic, neuropathic and traumatic ulcers in the patient absence of referral to the center for tracking and changing dressings. More than two turns
Age
From **30 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Individuals were randomly assigned into two groups of case and control with respect to entry and exit requirements.
Blinding (investigator's opinion)
Single blinded
Blinding description
The medical wounds of patients who were not aware of the dressing of patients and their placement in the case and control groups were evaluated and recorded in the checklist. Also, data analysis was performed by a statistical expert who was not aware of the case and control groups.
Placebo
Not used
Assignment
Parallel
Other design features
Comparison of interventional method with olive oil in diabetic foot ulcer with standard and standard methods for diabetic foot ulcer treatment.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hormozgan University of Medical Sciences
Street address
Chamran Blvd. Hormozgan University of Medical Sciences
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Bandar abbas
Province
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Postal code
7916613885
Approval date
2017-05-29, 1396/03/08
Ethics committee reference number
HUMS.REC.1396.24

Health conditions studied

1

Description of health condition studied
Diabetes mellitus
ICD-10 code
E11
ICD-10 code description
Diabetes mellitus

Primary outcomes

1

Description
Diabetic foot ulcer healing
Timepoint
4 weeks after intervention
Method of measurement
Diagnostic Foot ulcer Treatment Evaluation Checklist

Secondary outcomes

1

Description
Improve wound drainage
Timepoint
Weekly up to 4 weeks
Method of measurement
Wound assessment checklist

2

Description
Improve wound color
Timepoint
Weekly up to 4 weeks
Method of measurement
Wound assessment checklist

3

Description
Improve wound degree
Timepoint
Weekly up to 4 weeks
Method of measurement
Wound assessment checklist

4

Description
Improve wound around tissu
Timepoint
Weekly up to 4 weeks
Method of measurement
Wound assessment checklist

Intervention groups

1

Description
In the intervention group, ulcers and tissues around the wound were placed in the normal pelvic sterile saline for 20 minutes and then dried with sterilized gas. Afterwards, 2 cc of olive oil was poured onto the wound so that it covers the whole surface o
Category
Treatment - Drugs

2

Description
In the control group, ulcers and tissues around the wound were placed in the normal pelvic sterile saline for 20 minutes and then dried with sterilized gas. The surface of the wound was then dressed with a layer of gas. This was done once a day and seven
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Bandar Abbas Diabetes Clinic
Full name of responsible person
Dr Aminreza Abdoli
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Bandare-abbas 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
Bandare-abbas University of Medical Sciences

Full name of responsible person
Dr Aminreza Abdoli

Position
Internal medicine specialist

Latest degree
Specialist

Other areas of specialty/work
Internal Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Attached to the article is an article

When the data will become available and for how long
From year 1398

To whom data/document is available
Academic Institutions

Under which criteria data/document could be used
University professors

From where data/document is obtainable
Writers Email

What processes are involved for a request to access data/document
Email the authors and ask the request and the reason for the request

Comments