

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 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

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Hormozgan university of medical sciences

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

City

Bandar abbas

Province

Hormozgan

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

Bandare-abbas University of Medical Sciences

Full name of responsible person

Abd-alazim Nejatizadeh

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Vice Chancellor for Research, Shahid Mohammadi Hospital, Jomhori Blvd.

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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