

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The effect of topical olive oil on the healing of foot ulcer in patients with type 2 diabetes in Ahvaz diabetes clinic in 2013

Protocol summary

Summary

The purpose of this clinical trial study is to assess the effect of topical olive oil on the healing of foot ulcer in patients with type 2 diabetes. After obtaining informed consent from patients, 34 type 2 diabetic patients with diabetic foot ulcers of grade 1 and 2 in the feet, toes, heels and feet will select and randomly assign to groups of intervention and control. Classification of wound degree will perform using the Wegener criteria. Initially, in both groups wound wash based on routine procedures of hospital. Then wound in the intervention group will dress with olive oil and in the control group just simple gaze will use without any topical drug. This procedure will do once a day for 1 month in both groups. In the end of each week, the wound would be assessed and scored with diabetic ulcer healing check list by a specialist who is unaware of group's assignment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014083014251N2**

Registration date: **2014-09-05, 1393/06/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-09-05, 1393/06/14

Registrant information

Name

MORTEZA NASIRI

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 77 2622 5292

Email address

nasiri.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2014-04-04, 1393/01/15

Expected recruitment end date

2014-07-05, 1393/04/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of topical olive oil on the healing of foot ulcer in patients with type 2 diabetes in Ahvaz diabetes clinic in 2013

Public title

The effect of topical olive oil on the healing of foot ulcer in patients with type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: having a diabetic wound grade 1 and 2 based on Wegener's classification ; having foot ulcers in the extremities (fingers, soles, heels, or foot) that have created at least 4 weeks before ; having a body mass index 18 to 35 ; lack of any history of addiction and cigarette and alcohol abuse ; lack of using any drug that may delays wound healing such as: corticosteroids, immunosuppressive and cytotoxic agents ; lack of any chronic diseases other than diabetes that may affect the healing of wounds such as cancers, vacuities, liver and

kidney dysfunctions and heart failure class 3. Exclusion criteria: wound with active infection that needs antibiotic therapy and any gangrene wound that needs amputation; any evidence of ischemic, traumatic, neurotropic and venous ulcers; procrastinate refer to diabetes clinic for wound dressing change more than two times.

Age

From **30 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

Randomized

Randomization description**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**

Ahvaz Jundishapur University of Medical Sciences
Ethics Committee

Street address

Ahvaz Jundishapur University of Medical Sciences,
Ahvaz, Khozestan.

City

Ahvaz

Postal code**Approval date**

2014-05-31, 1393/03/10

Ethics committee reference number

ajums.REC.1393, 61

Health conditions studied**1****Description of health condition studied**

Diabetes

ICD-10 code

E10.7

ICD-10 code description

Insulin-dependent diabetes mellitus with multiple complications

Primary outcomes**1****Description**

Healing of diabetic foot ulcers

Timepoint

Weekly

Method of measurement

Based on diabetic foot ulcers check list

Secondary outcomes**1****Description**

Tissue around the wound

Timepoint

Weekly

Method of measurement

Based on diabetic foot ulcers check list

2**Description**

Wound degree

Timepoint

Weekly

Method of measurement

Based on diabetic foot ulcers check list

3**Description**

Wound exudates

Timepoint

Weekly

Method of measurement

Based on diabetic foot ulcers check list

4**Description**

Wound color

Timepoint

Weekly

Method of measurement

Based on diabetic foot ulcers check list

Intervention groups**1****Description**

In the intervention group, wound and tissues around the wound is placed in sterile saline container for 20 minutes and then dry with sterile gaze. Then 2 cc of olive oil will pour in the wound in a way that cover the entire surface of the wound. Then the wound would be dressed with a

layer of gaze with sterile technique. This procedure will do once in a day, and seven days of a week for 1 month.

Category

Treatment - Drugs

2

Description

In the control group, wound and tissues around the wound is placed in sterile saline container for 20 minutes and then dry with sterile gaze. Then the wound would be dressed with a layer of gaze with sterile technique. This procedure will do once in a day, and seven days of a week for 1 month.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes clinic of Golestan hospital

Full name of responsible person

Lila Yazdanpanah

Street address

Golestan hospital, Golestan road, Ahvaz, Khozestan.

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr. Ahmad Hosseini

Street address

Ahvaz Jundishapur University of Medical Sciences,
Golestan road, Ahvaz, Khozestan.

City

Ahvaz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz Jundishapur University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Morteza Nasiri

Position

MSc student of nursing education

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty