

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Effect of Kiwi fruit on diabetic foot ulcer healing process

Protocol summary

Study aim

Determining the effect of Kiwi on diabetic foot ulcer healing in diabetic patients referring to Diabetes Clinic of Rafsanjan

Design

In this analytical-interventional, clinical trial and double-blind study, 18 patients with diabetic foot ulcers referred to diabetic clinic of Ali ebn Abitaleb hospital in 2017 were enrolled. Patients who had taken antibiotic (whether injectable, oral or topical), had needed to urgent debridement, and Wagner's Benchmark 3 onward were excluded from the study. After obtaining the informed consent from all patients included in this study, all patients were divided randomly in control and experimental groups.

Settings and conduct

determine the initial size of the wound, a baseline photo of the wound was taken. Then all patients received standard treatment including debridement and antibiotic. after washing the wound , it dressed by eucerin. patients of the experimental group received the standard treatment (without debridement) and the ulcer of these patients were covered with a 3 mm-thick layer of a mixture of fresh kiwifruit and eucerin (1:1 for). The wounds of these group washed per 24 hours by sterile normal saline then they were covered again by kiwi cream and dressed with sterile gauze and latex-free tape. All ulcer macroscopic changes were recorded in both control and experimental groups during the study. The macroscopic changes in the ulcer size is evaluated every week. In addition, on each weekly visit, a photo of the wound was taken to record the ulcer size and healing process.

Participants/Inclusion and exclusion criteria

diabetic foot ulcer

Intervention groups

In addition to standard treatment in all patients, 3mm layer of eucerin cream Cream is laid on the wound (in control group). 3mm layer of eucerin cream Cream an kiwi (1:1) is laid on the wound (in case group).

Main outcome variables

area changes of diabetic foot ulcer

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160217026627N2**

Registration date: **2018-08-21, 1397/05/30**

Registration timing: **retrospective**

Last update: **2018-08-21, 1397/05/30**

Update count: **0**

Registration date

2018-08-21, 1397/05/30

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3428 0086

Email address

moeinkardost@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

2017-03-21, 1396/01/01

Actual recruitment end date

2018-03-21, 1397/01/01

Trial completion date

empty

Scientific title

Effect of Kiwi fruit on diabetic foot ulcer healing process

Public title

Kiwi fruit effect on diabetic foot ulcer

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All of patients with diabetic foot ulcer

Exclusion criteria:**Age**

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Actual sample size reached: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients with a probability of 1:2 in the throw of coins enter to the intervention and control groups

Blinding (investigator's opinion)

Double blinded

Blinding description

Before weekly visiting and photography; patients sore wash with normal saline serum, the type of topical drug is known.

Placebo

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Rafsanjan University of Medical Sciences

Street address

Imam Ali boulevard - central office of Rafsanjan University of Medical Sciences

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Approval date

2017-02-28, 1395/12/10

Ethics committee reference number

IR.RUMS.REC.1395.150

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

Diabetic foot ulcer

ICD-10 code

Z86.31

ICD-10 code description

Personal history of diabetic foot ulcer

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

healing progress of diabetic foot ulcer

Timepoint

ulcer area calculating before intervention, 1st,2nd and 3rd weeks after intervention

Method of measurement

digital camera

Secondary outcomes

empty

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

Intervention group: patients received standard treatment including debridement and oral antibiotic (ciprofloxacin 500 mg every 12 hours+ clindamycin 600 mg every 8 hours). after washing the wound by sterile normal saline, it dressed by oceerin cream (made by Farabi-Iran) regularly. The patients evaluated every week to assess the ulcer in term of rate recovery, appearance characterize and need or no need to surgical for debridement. The patient of the control group only received the standard treatment and the wound dressing was changed every day. The patient of the experimental group received the standard treatment (without debridement) along with additional treatment, which is as follows: the ulcer of these patients were covered with a 3 mm-thick layer of a mixture of pulped fresh kiwifruit and oceerin cream (ratio 1:1 for making cream) by using a 50 cc gavage syringe. The wounds of these group washed per 24 hours by sterile normal saline then they were covered again by kiwi cream and dressed with sterile gauze and latex-free tape.

Category

Treatment - Other

2

Description

Control group: patients received standard treatment including debridement and oral antibiotic (ciprofloxacin 500 mg every 12 hours+ clindamycin 600 mg every 8 hours). after washing the wound by sterile normal saline, it dressed by ocerin cream (made by Farabi-Iran) regularly. The patients evaluated every week to assess the ulcer in term of rate recovery, appearance characterize and need or no need to surgical for debridement. The patient of the control group only received the standard treatment and the wound dressing was changed every day.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

diabetic clinic of Ali ebn Abitaleb hospital

Full name of responsible person

Moein Kardoust Parizi

Street address

Imam Ali boulevard - Ali-ene-abitaleb Hospital

City

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Email

aliebn_hospital@rums.ac.ir

Web page address

<http://aliebn.rums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Hossein Salehi

Street address

Imam Ali boulevard - central office of Rafsanjan University of Medical Sciences

City

Rafsanjan

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Kerman

Postal code

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Email

info@rums.ac.ir

Web page address

<http://www.rums.ac.ir/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Moein Kardoust Parizi

Position

Medical doctor

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Moein Kardoust Parizi

Position

Medical doctor

Latest degree

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Title and more details about the data/document

-

When the data will become available and for how long

-

To whom data/document is available

-

Under which criteria data/document could be used

-

From where data/document is obtainable

-

What processes are involved for a request to access data/document

-

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Rafsanjan University of Medical Sciences

Full name of responsible person

Moein Kardoust Parizi

Position

Medical doctor

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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