Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 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.

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
Rafsanjan

Province
Kerman

Postal code
7717933777

Phone
+98 34 3428 0001

Fax
+98 34 3428 0022

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

Province
Kerman

Postal code
7717933777

Phone
+98 34 3428 0038

Fax
+98 34 3428 0071

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

Street address
Imam Ali boulevard - Ali-ene-abitaleb Hospital

City
Rafsanjan

Province
Kerman

Postal code
7717933777

Phone
+98 34 3428 0001

Fax
+98 34 3428 0022

Email
moeinkardost@rums.ac.ir

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
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
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City
Rafsanjan
Province
Kerman
Postal code
7717933777
Phone
+98 34 3428 0001
Email
moeinkardost@rums.ac.ir

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
Street address
Imam Ali boulevard - Ali-ene-abitaleb Hospital
City
Rafsanjan
Province
Kerman
Postal code
7717933777
Phone
+98 34 3428 0001
Fax
+98 34 3428 0022
Email
moeinkardost@rums.ac.ir

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