

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 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

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

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##### Postal code

7717933777

##### Phone

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##### 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

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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****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**

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