Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of Aloe vera jel on healing of first degree diabetic foot ulcer in patient who admitted in wound clinic Shahid mohammadi Hospital in bandar abbas

Protocol summary

Study aim
=The effect of Aloevera jel on healing of first degree diabetic foot ulcer in patient who admitted in wound clinic Shahid mohammadi Hospital

Design
Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

Settings and conduct
Intervention is at Shahid Mohammadi Hospital in Bandar Abbas. The wounds are washed daily with 0.9% normal saline. In the experimental group, after washing the wound with normal saline, aloe vera gel (a thin layer that covers the entire wound) is used. According to the hospital routine, the bandages are changed daily and examined. Wound Assessment Tool is a Bates-genus instrument that includes 15 items and examines the size, type and depth Blindness is double blind

Participants/Inclusion and exclusion criteria
Study inclusion criteria: 1- Diabetic foot ulcer with a size of less than 10 cm 2-Patients without a history of cancer, AIDS and severe skin allergies and skin problems 3- Do not smoke or drink alcohol 4- Do not use other materials for dressing 5- Patient age between 30 to 70 6- The interval between wounding and entering the study is less than one day 7- able to answer 8- Willingness to participate in the study Exclusion criteria: 1- History of allergy to aloe vera

Intervention groups
The wounds are whashed daily with 0.9% normal saline. In the intervention group, after washing the wounds with normal saline, aloe vera gel (a thin layer that covers the entire wound) is used. According to the hospital routine, the bandages are changed daily and examined.

Main outcome variables
Accelerate the healing of diabetic foot ulcers

General information

Reason for update

Acronym
aloe vera

IRCT registration information
IRCT registration number: **IRCT20141130020151N2**
Registration date: **2021-08-18, 1400/05/27**
Registration timing: **registered_while_recruiting**

Last update: **2021-08-18, 1400/05/27**
Update count: **0**

Registration date
2021-08-18, 1400/05/27

Registrant information

Name
Parichehr Sabaghzadeh Irani
Name of organization / entity
Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 000000
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-22, 1400/04/01

Expected recruitment end date
2021-08-23, 1400/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Aloe vera jel on healing of first degree diabetic foot ulcer in patient who admitted in wound clinic Shahid mohammadi Hospital in bandar abbas

Public title
The effect of Aloe vera jel on healing of first degree diabetic foot ulcer in patient who admitted in wound clinic Shahid mohammadi Hospital in bandar abbas

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with diabetic foot ulcers less than 10 cm in size Not more than one day has passed from the time of wounding to the time of hospitalization It does not have cancer, AIDS, severe skin allergies and skin problems Do not use cigarettes Be willing to participate in research The wound is not bandaged with any substance Do not use any substance other than 0.9% normal saline on the wound he patient should be between 30 and 70 years old Do not use alcohol be able to answer questions as well

Exclusion criteria:
History of allergy to aloe vera

Age
From **30 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description
First, the samples are entered into the study based on the inclusion criteria. Then the selection of the control group and the intervention is done by simple random method. Randomization tool is the use of opaque and similar cards. In this method, the word intervention is written on one card and the control card on the other. The cards are opaque and are quite similar in weight and appearance. The cards are then placed in front of the patient and the patient selects a card. This process continues until the sample size is reached.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients were unaware of the type of dressing. The filler questionnaire did not know the type of dressing

Placebo
Not used

Assignment
Parallel

Other design features
nothing

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of kerman University of Medical Sciences

Street address
Kerman University of Medical Sciences,Medical University Campus,Haft-Bagh Highway, Kerman, Iran

City
kerman

Province
Kerman

Postal code
7616913555

Approval date
2021-01-04, 1399/10/15

Ethics committee reference number
IR.KMU.REC.1399.567

Health conditions studied

1

Description of health condition studied
Patients with first degree diabetic foot ulcer

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
the wound tool score Bates-Jensen

Timepoint
Once every 7 days for 21 days

Method of measurement
the wound tool score Bates-Jensen

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:In the intervention group, first the wounds are washed daily with 0.9% normal saline, then a thin layer of aloe vera gel is used to cover the whole wound, then the wound is closed with a sterile gauze bandage. Dressings are changed daily for 21 days (three

weeks) and checked each time they are changed. At the end of each dressing (once a week), a wound examination tool is recorded. Aloe vera gel is produced by Barij Essential Oil Company.

Category

Treatment - Drugs

2

Description

Control group:In the control group, wounds after dressing with normal saline 0.9% are bandaged with sterile gauze and bandage. Dressings are changed daily for 21 days (three weeks) and checked each time they are changed. At the end of each dressing (once a week), a wound examination tool is recorded.roup:

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Mohamadi hospital

Full name of responsible person
MR yaser khanche mehr

Street address
Hormozgan Province, Bandar Abbas, Kuy e Farhangiyan, Payambar aazam medical educational complex

City
bandar abbas

Province
Hormozgan

Postal code
7614763154

Phone
+98 76 3334 7000

Fax

Email
shmh@hums.ac.ir

Web page address
http://shmh.hums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
dr. ababs pardakhti

Street address
Ebn-e-Sina St.,Jahad Blvd., Kernan,Iran

City
kerman

Province
Kerman

Postal code
7619813159

Phone
+98 34 3226 3855

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vcr@kmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman University of Medical Sciences

Proportion provided by this source

1

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
Kerman University of Medical Sciences

Full name of responsible person
parichehr sabaghzadeh irani

Position
PHD student

Latest degree
Master

Other areas of specialty/work
Nursery

Street address
Kerman University of Medical Sciences,Medical University Campus,Haft-Bagh Highway, Kerman, Iran

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Province
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7616913555

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
parichehr sabaghzadeh irani

Position
phd student

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

parichehr sabaghzadeh irani

Position

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Latest degree

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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

Yes - There is a plan to make this available

Title and more details about the data/document

All data is published in such a way that the names of the participants are not disclosed

When the data will become available and for how long

After printing the results and at the time of submission to the judges of the journals

To whom data/document is available

All members of the research team, all reviewers of journals whose work results are sent for publication, and all researchers

Under which criteria data/document could be used

In case of citing researchers, doing work is not prohibited

From where data/document is obtainable

parichehr sabaghzadeh irani

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

by Email

Comments