

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

The effect of Aloe vera gel 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 gel 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 washed 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)

Phone

+98 000000

Email address

parichehr_sabaghzadeh@yahoo.com

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 gel 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 gel 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.

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., Kerman,Iran

City

kerman

Province

Kerman

Postal code

7619813159

Phone

+98 34 3226 3855

Email

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

City

kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3132 5219

Email

parichehr_sabaghzadeh@yahoo.com

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

Street address

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

City

kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3132 5219

Email

parichehr_sabaghzadeh@yahoo.com

Phone

+98 34 3132 5219

Email

parichehr_sabaghzadeh@yahoo.com

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

Person responsible for updating data

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

City

kerman

Province

Kerman

Postal code

7616913555