

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Effecacy of Aloe Vera cream dressing on Healing of Diabetic Foot Ulcers: A Double-Blind, RandomizedClinical Trial Study

Protocol summary

Summary

The purpose of this clinical trial, Effects of Aloe vera cream dressing on healing diabetic foot ulcers. This study is arandomized and double blind. After obtaining informed consent from patients, 34 type 2 diabetic patients with diabetic foot ulcers of grade 1 and 2 in the feet, toes, heels and feet are chosen on the tiller. Wegener classification is performed using the of the degree of injury. Patients are randomly divided into 2 groups. Initially, both groups wound dressing method is routinely washed. Inclusion criteria: age 30-80 years and having HbA1C in the normal range (HbA1C <6.5) is the exit conditions of the study: cancer and cyto toxic drugs, Immunosuppressive consumption and chronic diseases of diabetes on the healing process is effective for severe wounds such as vascular disease, lupus, rheumatoid arthritis, kidney failure.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205289894N1**

Registration date: **2012-06-11, 1391/03/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-06-11, 1391/03/22

Registrant information

Name

Mohammad Maniey

Name of organization / entity

Ahvaz Jondishapor University of Medical Sciences,
International branch

Country

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jondishapour University of Medical Sciences

Expected recruitment start date

2012-02-14, 1390/11/25

Expected recruitment end date

2012-06-04, 1391/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effecacy of Aloe Vera cream dressing on Healing of Diabetic Foot Ulcers: A Double-Blind, RandomizedClinical Trial Study

Public title

Aloe Vera effect on diabetic foot ulcers

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: having a diabetic wound grade 1 and 2 based on Wegener's classification; foot ulcers in the extremities (fingers, soles, heels, on foot); having a body mass index 18 to 35; having full consciousness enrollment; age between 30 to 80 years old; patients with controled diabetes by diet and medication and HbA1C in the normal range (HbA1C <6.5). Exclusion criteria: drug and alcohol abuse; smoking; chronic diseases other than diabetes that may affect the healing of wounds such as severe cardiovascular disease, lupus,

rheumatoid arthritis, kidney failure; consumption immunosuppressive; cancer and taking cytotoxic drugs.

Age

From **30 years** old to **80 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ahvaz Jondishapor University of Medical Sciences
Ethics Committee

Street address

Ahvaz- Golestan street

City

Ahvaz

Postal code

Iran

Approval date

2012-02-12, 1390/11/23

Ethics committee reference number

ETH-446

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

Diabet

ICD-10 code

E-10

ICD-10 code description

Peripheral angiopathy in diseases classified elsewhere

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

Healing of diabetic foot ulcers

Timepoint

weekly

Method of measurement

Evaluation of diabetic foot ulcers based on check list

Secondary outcomes**1****Description**

Reduce the size of wound exudate

Timepoint

Weekly

Method of measurement

Check list

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

In the intervention group, wound and scar tissue around the wound is placed in sterile saline container for 20 minutes. Then will be used of Aloe vera cream 15 percent. So that after washing the wound, a thin layer of cream over the entire surface of the wound is placed Aloe vera and then putting a layer of gas is sterile technique and dressing it twice day, seven days a week will do.

Category

Treatment - Drugs

2**Description**

In the control group, wound and scar tissue around the wound placed in sterile saline container for 20 min and then dried with sterile gauze. After washing the wound, a thin layer of placebo over the entire surface of the wound and then put a layer of gas, sterile dressing method and this work will be done twice a day and seven days a week.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Dr. Gangavian Hospital

Full name of responsible person

Mohammad Maniey

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jondishapor University of Medical Sciences

Full name of responsible person

Dr. Mostafa Fegghi

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz Jondishapor University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Ahvaz Jondishapor Medical Sciences Inter National Unit

Full name of responsible person

Fahimeh Sabeti

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty