

# 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

Iran (Islamic Republic of)

##### Phone

+98 64 1526 8774

##### Email address

mohammadmaniey@yahoo.com

##### 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

**Street address**

Dezful-Andimeshk road

**City**

Dezful

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Ahvaz Jondishapor University of Medical Sciences

**Full name of responsible person**

Dr. Mostafa Fegghi

**Street address**

Ghvaz-Golestan road

**City**

Ahvaz

**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

**Position**

Senior experts of Nursing - Director of Nursing Faculty Abadan

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

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MS in Nursing

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

Mohammad Maniey

**Position**

Nursing Student

**Other areas of specialty/work**

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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*