

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The survey of affect of aloe Vera anti-ulcer cream and infrared radiation therapy on diabetic foot ulcer

#### Protocol summary

##### Summary

The aim of this study is to survey of affect of aloe Vera anti-ulcer cream after infrared radiation therapy on diabetic foot ulcer. In this randomized clinical trial, a total of 50 participants (enrolled into two groups with Randomize allocated and layout blocks based on gender) were recruited from a tertiary clinic in Dezful (Dr Ganjavian Hospital). The patients aged between 30 and 80 years and were diagnosed with grade I and II foot ulcer based on the Wagner wound classification. Control group received just standard wound care for diabetic foot ulcers and Intervention group received aloe Vera anti-ulcer cream after infrared radiation therapy in addition of standard wound care. The wound surface area is determined as the primary outcome. In this study data will collect by tools included demographic questionnaire and evaluate the chronic wound healing checklist (bets Jensen tool). Patients were followed for 1 month weekly and compared in term of rate of healing.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201504119894N2**  
Registration date: **2016-03-22, 1395/01/03**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-03-22, 1395/01/03

##### 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

Vice chancellor for research, Dezful University of Medical Sciences

##### Expected recruitment start date

2016-03-10, 1394/12/20

##### Expected recruitment end date

2018-03-11, 1396/12/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The survey of affect of aloe Vera anti-ulcer cream and infrared radiation therapy on diabetic foot ulcer

##### Public title

The affect of aloe Vera cream and infrared radiation therapy on diabetic foot ulcer

##### 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 smallest than 8).

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 immuno suppressive; 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: **50**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Not blinded

#### **Blinding description**

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Dezful University of Medical Sciences

##### **Street address**

Next to the Police Department, Azadegan Blv, Dezful University of Medical Sciences, Dezful, Khozestan, Iran Dezful Khozestan

##### **City**

Dezful

##### **Postal code**

#### **Approval date**

2015-08-20, 1394/05/29

#### **Ethics committee reference number**

lr.dums.rec.1394.8

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Diabetes mellitus

#### **ICD-10 code**

E10

#### **ICD-10 code description**

Insulin-dependent diabetes mellitus

## **Primary outcomes**

### 1

#### **Description**

Ulcer size

#### **Timepoint**

Every week, for 4 weeks

#### **Method of measurement**

Bets jensen chronic ulcer tools

## **Secondary outcomes**

### 1

#### **Description**

Wound healing

#### **Timepoint**

Every week, for 4 weeks

#### **Method of measurement**

Bets jensen chronic ulcer tools

## **Intervention groups**

### 1

#### **Description**

Patients in the intervention group, the wound is irrigated with normal saline and then after infrared radiation therapy using topical Aloe Vera gel that is placed on the wound dressing and the band dressing up to be a period of 28 days will be carried out once a day

#### **Category**

Rehabilitation

### 2

#### **Description**

Patients in the control group, the wound is irrigated with normal saline and then put some control on the wound with gauze and bandages are dressing once a day for 28 day

#### **Category**

Rehabilitation

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Dezful Hospital, Dezful University Of Medical Sciences

##### **Full name of responsible person**

Hamidreza Aghababaeian

##### **Street address**

Next to the Police Department, Azadegan Blv, Dezful University of Medical Sciences, Dezful, Khozestan, Iran Dezful Khozestan

##### **City**

## Sponsors / Funding sources

**1**

### Sponsor

**Name of organization / entity**

Vice chancellor for research, Dezful University Of Medical Sciences

**Full name of responsible person**

Feridon Nirozad

**Street address**

Next to the Police Department, Azadegan Blv, Dezful University of Medical Sciences, Dezful, Khozestan, Iran Dezful Khozestan

**City**

Dezful

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice chancellor for research, Dezful 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**

Dezful University Of Medical Sciences

**Full name of responsible person**

Hamidreza Aghababaeian

**Position**

Faculty member

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

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**Other areas of specialty/work**

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**Fax**

**Email**

**Web page address**

## 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*

