

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

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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

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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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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

