Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
Ir.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

Dezful

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
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Faculty member
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Person responsible for updating data

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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*