Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

The effect of Aloe vera and Plantago Major gel in Diabetic Foot Ulcers in patients with type 2 diabetes.

Protocol summary

Summary

The purpose of this study was to determine the effect of Traditional Medicine product to improve type 2 diabetic patients are Diabetic foot ulcer. This study is a double blind randomized clinical trial on Diabetic foot ulcer patients without underlying disease conditions under which the entry and exit is included. Inclusion criteria: Type II diabetes for at least 5 years; Age between 30 to 65 years; BMI greater than 18 and less than 35; Diagnosis of Neuropathic diabetic foot ulcer Wagner grade 1 or 2 Moderate infections by Internal expert; HbA1C <10; Exclusion criteria: Lack of patient follow-up; Lack of satisfaction in every stage of the study; Failure to respond to treatment; Create complications in the study conducted by treatment; Acute or severe complications of diabetes, exacerbation of underlying disease; Other systemic diseases that may have an impact Wound Development such as chronic renal failure, liver failure, congestive heart failure; Tobacco, Alcohol, Cytotoxic, Glucocorticoid, Immunosuppressive drugs; Pregnancy and lactation; Sensitivity to Aloe vera and Plantago Major plants; Diabetic foot ulcer grade 3 to 5 Wagner; Suspected osteomyelitis (lesion size of more than 2 square centimeters). The total number of 40 patients is taken into account that randomly will be divided into two groups: intervention and control. The control group will be used the classic medicine and topical placebo 2 times a day for 28 days . In the intervention group will be used in addition to the classic medicine, Aloe vera and Plantago Major 10% gel 2 times a day for 28 days. The main outcome measure of the study is the wound area, depth of the wound, ulcer symptoms (secretion, edema, erythema and scaling) and related consequences outcome is laboratory tests included CBC, FBS, 2HPP, HbA1c, Urea and Cr. Candidates are tested at twice. The first time before entering the study and the second time after the end of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016072629078N1**
Registration date: **2016-10-08, 1395/07/17**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-10-08, 1395/07/17

Registrant information

Name

Yones Najafian Razavi

Name of organization / entity

Faculty of Iranian Traditional Medicine and Complementary of Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3845 9422

Email address

najafiany921@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research and Technology Vice-Chancellory of Mashhad University of Medical Sciences

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2017-10-23, 1396/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of Aloe vera and Plantago Major gel in Diabetic Foot Ulcers in patients with type 2 diabetes.

Public title
The effects of Traditional medicine product in Diabetic Foot Ulcer

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Type II diabetes for at least 5 years; Age between 30 to 65 years; BMI greater than 18 and less than 35; Diagnosis of neuropathic diabetic foot ulcer Wagner grade 1 or 2 Moderate infection by Internal expert; HbA1C <10; Exclusion criteria: Lack of patient follow-up; Lack of satisfaction in every stage of the study; Failure to respond to treatment; Create complications in the study conducted by treatment; Acute or severe complications of diabetes, exacerbation of underlying disease; Other systemic diseases ; Tobacco, Alcohol, Cytotoxic, Glucocorticoid, Immunosuppressive drugs; Pregnancy and lactation; Sensitivity to Aloe vera and Plantago Major plants; Diabetic foot ulcer grade 3 to 5 Wagner; Suspected osteomyelitis (lesion size of more than 2 square centimeters)

Age
From **30 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **40**

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
Ethics committee of Mashhad University of Medical Sciences

Street address
Daneshgah Ave, Building Qureshi, Mashhad University of Medical Sciences Administration

City
Mashhad

Postal code

Approval date
2016-06-18, 1395/03/29

Ethics committee reference number
IR.MUMS.REC.1395.199

Health conditions studied

1

Description of health condition studied
Diabetic Foot Ulcer

ICD-10 code
E10.5

ICD-10 code description
Insulin-dependent diabetes mellitus with peripheral circulatory complications

Primary outcomes

1

Description
The area of the wound

Timepoint
Baseline, the end of the study

Method of measurement
Ruler and Imaging

2

Description
Deep wounds

Timepoint
Baseline, the end of the study

Method of measurement
A sterile swab

3

Description
Wound symptoms

Timepoint
Baseline, the end of the study

Method of measurement
Secretion, Edema, Erythema And Desquamation

Secondary outcomes

1

Description
HbA1c

Timepoint
Baseline, the end of the study

Method of measurement

Laboratory blood test

2

Description
Urea
Timepoint
Baseline, the end of the study
Method of measurement
Laboratory blood test

3

Description
2Hpp
Timepoint
Baseline, the end of the study
Method of measurement
Laboratory blood test

4

Description
CBC
Timepoint
Baseline, the end of the study
Method of measurement
Laboratory blood test

5

Description
FBS
Timepoint
Baseline, the end of the study
Method of measurement
Laboratory blood test

6

Description
Blood pressure
Timepoint
Baseline, the end of the study
Method of measurement
Manometer

7

Description
Creatinine
Timepoint
Baseline, the end of the study
Method of measurement
Laboratory blood test

Intervention groups

1

Description
In the control group, placebo topical (gel containing only basis) also trained twice a day by the patient or the patient up to 28 days to five millimeters in diameter is applied on the wound and finally covered with sterile gauze and tape is latex-free.
Category
Placebo

2

Description
In the intervention group Aloe vera 10% gel and Hydroalcholic extract of leave of Plantago Major (Aloe Vera 5% resin and Plantago Major 5% extract) with trained twice a day by the patient or the patient up to 28 days to five millimeters in diameter is applied on the wound and finally covered with sterile gauze and tape is latex-free.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Diabetic Foot Clinic of Imam Reza Hospital in Mashhad
Full name of responsible person
Yones Najafian Razavi
Street address
East Razi Ave, Opposite the Mehran sports hall, Faculty of Iranian Traditional Medicine and Complementary
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research and Technology Vice-Chancellory of Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Daneshgah Ave, Building Qureshi, Mashhad University of Medical Sciences Administration
City
Mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research and Technology Vice-Chancellory of Mashhad 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

Faculty of Iranian Traditional Medicine and Complementary of Mashhad University of Medical Sciences

Full name of responsible person

Yones Najafian Razavi

Position

PhD student of Iranian Traditional Medicine and Complementary

Other areas of specialty/work

Street address

East Razi Ave, Opposite the Mehran sports hall, Faculty of Iranian Traditional Medicine and Complementary

City

Mashhad

Postal code

Phone

+98 51338552188

Fax

Email

najafiany921@mums.ir; yones_dr@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty of Iranian Traditional Medicine and Complementary of Mashhad University of Medical Sciences

Full name of responsible person

Zohre Feyzabadi

Position

Assistant Professor

Other areas of specialty/work

Street address

East Razi Ave, Opposite the Mehran sports hall, Faculty of Iranian Traditional Medicine and Complementary

City

Mashhad

Postal code

Phone

+98 51 3855 2188

Fax

Email

Feyzabadiz@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Faculty of Iranian Traditional Medicine and Complementary of Mashhad University of Medical Sciences

Full name of responsible person

Yones Najafian Razavi

Position

PhD student of Iranian Traditional Medicine and Complementary

Other areas of specialty/work

Street address

East Razi Ave, Opposite the Mehran sports hall, Faculty of Iranian Traditional Medicine and Complementary

City

Mashhad

Postal code

Phone

+98 51 3855 2188

Fax

Email

najafiany921@mums.ir; yones_dr@yahoo.com

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

Data Dictionary

empty