

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of Aloe Vera Gel and Lawsoniainermis leaves extracts on the healing process of diabetic foot ulcers.

Protocol summary

Study aim

Determining the effect of aloe vera gel and Lawsoniainermis leaves on the healing process of diabetic foot ulcers

Design

Clinical trial with control and intervention groups, double blind, random sampling available

Settings and conduct

Random sampling is available in patients referred to the 9day hospital who are candidates for diabetic foot ulcers. Neither analyst nor participant will be informed about group allocation. In group A, 20 patients with one centimeter of aloe vera gel in the daily dressing, In group B, 20 individuals with one cc of Lawsoniainermis leaves extract in daily dressing And in the control group, 20 people with one centimeter of hydrogel in daily dressing as placebo, Within 6 weeks, their foot ulcers will be treated locally. After two, four and six weeks of treatment, the extent of the wound and the healing process will be evaluated and recorded by the wound specialist.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with type 2 diabetes, men and women aged 45-85 years, with multiple or single scars lasting at least four weeks and Second-degree diabetic foot ulcers based on wagner classification. Exclusion criteria: Acute diabetic foot ulcers, Grade 3 and 4 and 5 diabetic foot ulcers, using of drugs that may interfere with wound healing such as Corticosteroid, immunosuppressive and cytotoxic agents and sensitivity to the herbal remedies used in the study.

Intervention groups

In intervention group A, 20 patients with one centimeter of aloe vera gel in the daily dressing, In intervention group B, 20 individuals with one cc of Lawsoniainermis leaves extract in daily dressing And in the control group, 20 people with one centimeter of hydrogel in daily dressing as placebo, Within 6 weeks, their foot ulcers will be treated locally.

Main outcome variables

The effect of aloe vera gel and Lawsoniainermis leaves extract on improving diabetic foot ulcer

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160516027925N5**

Registration date: **2020-04-25, 1399/02/06**

Registration timing: **prospective**

Last update: **2020-04-25, 1399/02/06**

Update count: **0**

Registration date

2020-04-25, 1399/02/06

Registrant information

Name

Amir Zoka

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3822 4395

Email address

zokaa921@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of Aloe Vera Gel and Lawsoniainermis leaves extracts on the healing process of diabetic foot ulcers.

Public title
"The effect of aloe vera and Lawsoniainermis on the healing process of diabetic foot ulcers.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients with type 2 diabetes Men and women in the age range of 45-85 years Patients with multiple or single wounds that have been present for at least four weeks Second-degree diabetic foot ulcers based on wagner classification
Exclusion criteria:
 Acute diabetic foot ulcers Grade 3 and 4 and 5 diabetic foot ulcers using of drugs that may interfere with wound healing such as Corticosteroid, immunosuppressive and cytotoxic agents sensitivity to the herbal remedies used in the study

Age
From **45 years** old to **85 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomized (using Randomization.com site) will be divided into three groups A (intervention), B (intervention) and C (control).

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants will not know which group they are in. The data analyst and the outcome assessor will also be unaware of which intervention group and which control group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Torbate Heydariye University of Medical science

Street address

University of medical science, Razi Street

City

Torbat Heydariyeh

Province

Razavi Khorasan

Postal code

9016910169

Approval date

2020-01-18, 1398/10/28

Ethics committee reference number

IR.THUMS.REC.1398.038

Health conditions studied

1

Description of health condition studied

Diabetic foot ulcer

ICD-10 code

E10.7

ICD-10 code description

Insulin-dependent diabetes mellitus with multiple complications

Primary outcomes

1

Description

Healing of diabetic foot ulcers

Timepoint

After two, four and six weeks of treatment

Method of measurement

Evaluation of diabetic foot ulcers based on check list

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1:Twenty patients with one centimeter of aloe vera gel in their daily dressing, their foot ulcers are treated topically for six weeks.

Category

Treatment - Other

2

Description

Intervention group 2: Twenty people with one cc of Lawsonia inermis leaves extracts in daily dressing, their foot ulcers are treated topically for six weeks.

Category

Treatment - Other

3

Description

Control group: Twenty people with one centimeter of hydrogel in a daily dressing as a placebo, their foot ulcers are treated for six weeks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

9day hospital Torbat Heydariyeh

Full name of responsible person

Hosein Azizi

Street address

Kashani Street, 9day hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Torbate-Heidaria University of Medical Sciences

Full name of responsible person

Hasan Azhdari Zarmehri

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Torbate-Heidaria University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Torbate-Heidaria University of Medical Sciences

Full name of responsible person

Hossein Bakhtiari Dovombaygi

Position

Undergraduate Nursing Student

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity

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Hosein Azizi

Position

Non-faculty physician

Latest degree

Specialist

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Traditional Medicine

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

Undergraduate Nursing Student

Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available