Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of Arnebia euchroma ointment effect in healing diabetic foot ulcers compared to simple dressings

Protocol summary

Study aim

Given the existence of some evidence of the healing effect of the root of the Abu Khalsa plant on some types of wounds and the lack of human studies on this subject on diabetic foot ulcers, and on the other hand, the high prevalence of this type of wound and its consequences, as well as the challenges in its treatment, this study was designed to investigate the effect of this plant on this type of wound so that if positive results are observed, this product can be introduced as an effective treatment for this disorder.

Design

A controlled, parallel-group, unblinded, randomized, phase 3 clinical trial on 60 patients. A block method was used for randomization.

Settings and conduct

Before the start of the aforementioned interventions, the wound size is determined and recorded as the product of the largest length and the largest width of the wound in centimeters. At the end of days 10 and 21 (end of the intervention), the wound size is determined and recorded again, and the percentage of size change is calculated using statistical formulas

Participants/Inclusion and exclusion criteria

Inclusion criteria: Grade 2 diabetic foot ulcer Exclusion criteria: -Hb A1C less than 10 -Use of broad-spectrum oral antibiotics during this period of wound treatment -No abscess or swelling in the wound area

Intervention groups

For the test group, Abu Khalsa ointment will be applied to create a 3 mm thick layer on sterile gauze and placed on the wound surface, once a day along with dressing and other routine care . . For the control group, simple dressing, once a day and routine care, as well as administration of oral antibiotics, will be prescribed for 2 weeks.

Main outcome variables

Wound size Percentage change in wound size

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250728066662N1**
Registration date: **2025-09-01, 1404/06/10**
Registration timing: **registered_while_recruiting**

Last update: **2025-09-01, 1404/06/10**
Update count: **0**

Registration date

2025-09-01, 1404/06/10

Registrant information

Name

Monireh Seraj

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 4274 7977

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-08-23, 1404/06/01

Expected recruitment end date

2025-11-22, 1404/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Arnebia euchroma ointment effect in healing diabetic foot ulcers compared to simple dressings

Public title
Evaluation of Havachobe ointment effect in healing diabetic foot ulcers
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having a grade 2 diabetic foot ulcer in one or more areas
Exclusion criteria:
-Currently smoking Taking anticoagulant medication in the last 3 months Taking immunosuppressive medication in the last 3 months Having a coagulation disorder such as hemophilia Taking medications or supplements containing vitamin C, A or ZINK in the last 3 months Having chronic vascular insufficiency with a cause other than diabetes Hb A1C more than 10 No taking broad-spectrum oral antibiotics during this period of wound treatment Abscess or swelling in the wound area
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization method will be performed using blocks of 4. So that all possible sequences of two drug and two placebo in each block will be made with each block being numbered. Then, using random number table, the blocks will be selected randomly and the patients will be assigned to the two groups of drug and placebo according to the the blocks sequences.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Qom University of Medical Sciences
Street address
Shahid Lavasani Street, Qom University of Medical Sciences
City
Qom
Province
Ghoum
Postal code
3713649373
Approval date
2025-07-27, 1404/05/05
Ethics committee reference number
IR.MUQ.REC.1404.092

Health conditions studied

1

Description of health condition studied
Diabetic foot ulcer
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Wound size
Timepoint
Before the start of the aforementioned interventions, the wound size is determined and recorded as the product of the largest length and the largest width of the wound in centimeters, as well as the presence or absence of erythema (redness) around the wound. At the end of days 10 and 21 (end of the intervention), the wound size is determined and recorded again.
Method of measurement
Ruler

Secondary outcomes

1

Description
Number of cases of erythema
Timepoint
Before the start of the aforementioned interventions, the wound size is determined and recorded as the product of the largest length and the largest width of the wound in centimeters, as well as the presence or absence of erythema (redness) around the wound. At the end of days 10 and 21 (end of the intervention), the wound size is determined and recorded again.
Method of measurement
Observation and photography

Intervention groups

1

Description
Intervention group: Abu Khalsa ointment was applied in the amount necessary to create a 3 mm thick layer on sterile gauze and placed on the wound surface.
Category
Treatment - Drugs

2

Description
Control group: Only simple dressings are used
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospital
Full name of responsible person
Monireh Seraj
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Soffe Boulevard, Al-Zahra Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ghoum University of Medical Sciences
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Vice President of Research and Technology
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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
Ghoum 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
Ghoum University of Medical Sciences
Full name of responsible person
Monireh Seraj
Position
Resident
Latest degree
Medical doctor
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