Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effects of Elaeagnus angustifolia extract gel with crocin-loaded nanohydroxyapatite versus standard care on diabetic foot ulcer healing.

Protocol summary

Study aim
Comparing the effects of Elaeagnus angustifolia extract gel with crocin-loaded nanohydroxyapatite versus standard care on diabetic foot ulcer healing.

Design
A controlled clinical trial with parallel groups, phase 0, was conducted on 30 patients. The rand function of Excel software was used for randomization.

Settings and conduct
Patients meeting the inclusion criteria will participate in the study. At every visit, wounds will be washed with sterile saline, with debridement as needed. Afterward, a thin gel layer will be applied daily to the wound for 20 days. Patients will receive daily follow-ups until healing is complete, with wound photographs taken every 10 days. The study takes place at the wound clinic of Imam Reza Hospital in Birjand.

Participants/Inclusion and exclusion criteria
This study focuses on patients with diabetic foot ulcers in Wagner stages 1 and 2, without clinical signs of infection, with controlled blood sugar and A1C levels, and who provide consent to participate in the study process, evaluation, and follow-up. Patients are excluded if they have recently undergone radiation or chemotherapy, are suspected of malignancy or other ulcer causes, or are pregnant or breastfeeding.

Intervention groups
Control group: This group consists of patients with diabetic foot ulcers in stages 1 and 2 according to the Wagner scale. In addition to controlling blood sugar, their wounds are washed and dressed. • Treatment group: In addition to washing and dressing the wounds, this group is advised to apply topically once a day an Elaeagnus angustifolia extract gel containing crocin-loaded nanohydroxyapatite to the wound for faster healing.

Main outcome variables
Wound healing rate; healing time; side effects; patient satisfaction; changes in wound size

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20250426065477N1**
Registration date: **2025-05-14, 1404/02/24**
Registration timing: **prospective**

Last update: **2025-05-14, 1404/02/24**
Update count: **0**

Registration date
2025-05-14, 1404/02/24

Registrant information
Name
Ehsaneh Azaryan
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-09-11, 1404/06/20
Expected recruitment end date
2026-08-11, 1405/05/20
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the effects of Elaeagnus angustifolia extract gel with crocin-loaded nanohydroxyapatite versus standard care on diabetic foot ulcer healing.

Public title
Investigation of the Effect of Elaeagnus angustifolia Extract Gel Containing Nanohydroxyapatite Loaded with Crocin in the Treatment of Diabetic Ulcers

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with diabetic foot ulcers who are in Wagner stage 1 or 2. have no clinical signs of infection. have controlled blood sugar and A1C levels. Willing to sign a consent form and agree to the study process, evaluation, and follow-up.

Exclusion criteria:
Patients who have recently received radiation or chemotherapy. Patients with suspected malignancy or other ulcer formation. Patients who are pregnant or breastfeeding. Patients with infected wounds.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
0

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
In this research design, to randomize the selection of patients with diabetes, first, a list of eligible patients is prepared, which includes information such as age, sex, type of diabetes, and severity of ulcers. Then, using a randomization software or random number table, the patients are divided into two groups: the first group receives treatment with elderberry extract gel containing crocin-loaded nanohydroxyapatite, and the second group receives standard treatment.

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
Birjand University of Medical Sciences (Research Ethics Committee)

Street address
Ghaffari Street

City
Birjand

Province
South Khorasan

Postal code
۹۷۱۷۸۵۳۰۷۶

Approval date
2025-01-27, 1403/11/08

Ethics committee reference number
IR.BUMS.REC.1403.416

Health conditions studied

1

Description of health condition studied
Diabete

ICD-10 code
E08

ICD-10 code description
Diabetes mellitus due to underlying condition

Primary outcomes

1

Description
Wound healing

Timepoint
Day Zero, Day 10, Day 20

Method of measurement
Square millimeter

Secondary outcomes

empty

Intervention groups

1

Description
Control group: This group includes patients with diabetic foot ulcers who are in stages 1 and 2 on the Wagner scale, and in addition to controlling blood sugar, their wounds are washed and dressed.

Category
Treatment - Other

2

Description

Intervention group: In addition to washing and dressing the wound, this group is advised to apply topically an Elaeagnus angustifolia extract gel containing crocin-loaded nanohydroxyapatite once a day for faster wound healing.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Specialized Wound Clinic, Imam Reza Hospital, Birjand

Full name of responsible person
Ehsaneh Azaryan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name
Grant, Young Assistant Professor, Deputy Director of Research and Technology, Ministry of Health

Grant code / Reference number
6755

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Deputy Director of Research and Technology, Ministry of Health

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
Birjand University of Medical Sciences

Full name of responsible person
Ehsaneh Azaryan

Position
Assistant Professor

Latest degree
Ph.D.

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Person responsible for updating data

Contact

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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