

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Preparation of ointment containing *Echium italicum* root extract and evaluation of its effect on diabetic foot ulcer: A randomized controlled clinical trial

Protocol summary

Study aim

Evaluation of the effectiveness of *Echium italicum* root extract topical ointment on diabetic foot ulcer

Design

Two arm parallel group randomised trial with control group

Settings and conduct

The study will be performed in Al-Zahra hospital of Isfahan. Patients with the inclusion criteria will be randomly assigned to drug (*Echium italicum*) or control groups. For patients in drug group, *Echium italicum* root extract topical ointment will be applied for two weeks, while for patients of control group, specific dressing (Aquacel-Ag) will be used for two weeks. Before any intervention, the wound size as the product of the longest length and width as well as the presence or absence of erythema around the wound will be determined and recorded. At the end of 7th and 14th day of intervention, the percent of wound size reduction and the erythema status will be recorded. Furthermore, the number of cases with complete wound healing during the study will be recorded for both groups. Finally, the mentioned variables will be compared between the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Diabetic foot ulcer grade 1 or 2

Exclusion criteria: 1. Smoking 2. Coagulopathy

Intervention groups

Drug Group: Topical ointment of *Echium italicum* root extract (made by faculty of pharmacy of Isfahan university of medical sciences), once daily concurrent with routine wound care including irrigation with normal saline solution, dressing, and antibiotic administration, if necessary, for two weeks Control Group: Specific dressing (Aquacel-Ag), once daily concurrent with routine wound care including irrigation with normal saline solution, dressing, and antibiotic administration, if

necessary, for two weeks

Main outcome variables

Percentage reduction in wound size

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150721023282N26**

Registration date: **2023-08-11, 1402/05/20**

Registration timing: **registered_while_recruiting**

Last update: **2023-08-11, 1402/05/20**

Update count: **0**

Registration date

2023-08-11, 1402/05/20

Registrant information

Name

Rasool Soltani

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 7067

Email address

soltani@pharm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-22, 1402/04/31

Expected recruitment end date

2023-10-22, 1402/07/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Preparation of ointment containing Echium italicum root extract and evaluation of its effect on diabetic foot ulcer: A randomized controlled clinical trial

Public title
Effect of Echium italicum root extract in diabetic foot ulcers

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Grade 1 or 2 diabetic foot ulcers in one or more areas
Exclusion criteria:
Smoking Use of Anticoagulant Drugs Within the Last 3 Months

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: 22

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization method using blocks of size 4 will be used. 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 Zabol University of Medical

Sciences

Street address
Vice-chancellery for research, zabol University of Medical Sciences, shahid-Rajaei Avenue, zabol

City
zabol

Province
Sistan-va-Balouchestan

Postal code
9861615881

Approval date
2023-04-18, 1402/01/29

Ethics committee reference number
IR.ZBMU.REC.1402.001

Health conditions studied

1

Description of health condition studied

diabetic foot ulcer

ICD-10 code

E11.621

ICD-10 code description

Type 2 diabetes mellitus with foot ulcer

Primary outcomes

1

Description

Ulcer reduction percentage

Timepoint

The beginning of the intervention 7 and 14 days after the intervention

Method of measurement

Ruler

Secondary outcomes

1

Description

The number of cases of erythema around the ulcer

Timepoint

The beginning of the intervention 7 and 14 days after the study

Method of measurement

Observation

Intervention groups

1

Description

Intervention group: Intervention group, ointment containing Echium italicum root extract (the amount needed to create a layer 3 mm thick on sterile gauze and placed on the wound surface, so as to cover the entire wound surface), once a day with dressing and other routine care including Debridement, rinsing with normal

saline and antibiotics will be prescribed for 2 weeks if necessary and blood sugar control. The wound will be washed before applying the gel

Category

Treatment - Drugs

2

Description

Control group: The control group will be given a new dressing (the type of which will be determined based on the type of wound and only one of them will be included in the study) once a day and routine care for 2 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Rasool Soltani

Street address

Al-Zahra hospital, Soffeh Blvd

City

Isfahan

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Isfahan

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8174675731

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alzahra@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zabol University of Medical Sciences

Full name of responsible person

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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

Zabol 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

Esfahan University of Medical Sciences

Full name of responsible person

Rasool Soltani

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

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Position

Professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

It is not necessary

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available