Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Phase I&II study of clinical trial safety and efficacy assessment of ointment made from extracted Shikonin in Alosa branschnikowi and Pusa capsica in patients with diabetic foot ulcers.

Protocol summary

Study aim

Phase I&II study of clinical trial safety and efficacy assessment of ointment made from extracted Shikonin in Alosa branschnikowi and Pusa capsica in patients with diabetic foot ulcers.

Design

A randomized clinical trial with a control group, with parallel groups, on 40 patients. R software will be used to generate random numbers.

Settings and conduct

The study population of the research includes all patients with chronic diabetic ulcers who visited Rasht Velayat and Imam Ardabil Hospitals were treated in the period of February 1401 to the end of January 1402, as well as people who referred to clinics.

Participants/Inclusion and exclusion criteria

Inclusion:Having a chronic diabetic foot ulcer on an outpatient basis,Age range from 30 to 80 years,Having a single wound in the legs and extremities that has not healed for at least 4 weeks,Having a body mass index of 18-35.Exclusion:The presence of a wound with an active infection requires receiving intravenous antibiotics, gangrene requiring amputation, smoking, alcohol and drug addiction, taking drugs that may interfere with wound healing, having a concurrent disease that may cause interfere in wound healing. .

Intervention groups

The control group received traditional treatment including washing twice a day with normal saline and keeping the wound clean and dry ,and bandaging with sterile gauze if necessary. In addition to the treatments of the control group, the intervention group uses the ointment considered by the plan.

Main outcome variables

Local infection; degree and size of the wound; granulation formation; Duration of complete wound healing; wound infection control.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230111057111N1**
Registration date: **2023-01-26, 1401/11/06**
Registration timing: **prospective**

Last update: **2023-01-26, 1401/11/06**
Update count: **0**

Registration date

2023-01-26, 1401/11/06

Registrant information

Name

Amin Bakhshizadeh Imcheh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3342 3240

Email address

info@iauardabil.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-31, 1401/11/11

Expected recruitment end date

2024-01-01, 1402/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Phase I&II study of clinical trial safety and efficacy assessment of ointment made from extracted Shikonin in Alosa branschnikowi and Pusa capsica in patients with diabetic foot ulcers.

Public title
Investigating the effect of herbal and animal ointment in diabetic foot ulcer patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having a chronic diabetic foot ulcer on an outpatient basis Age range from 30 to 80 years Having a single wound in the legs and extremities (fingers, soles, heels, on the toes) that has not healed for at least 4 weeks Having a body mass index of 18-35
Exclusion criteria:
The presence of a wound with an active infection requires receiving intravenous antibiotics Gangrene requiring amputation Smoking, alcohol and drug addiction Taking drugs that may interfere with wound healing, such as corticosteroids, immunosuppressive agents, and cytotoxic agents. Having concurrent disease
Age
From **30 years** old to **80 years** old
Gender
Both

Phase
1-2
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
in this research, in order to allocate patients to intervention and control groups, a block randomization approach will be used in a parallel way and random allocation rule. We will consider the size of the blocks randomly with a size of 4 or 6 , and various packages available in R software will be used to generate random numbers. The output of odd numbers will be classified in the intervention group and the output of even numbers will be classified in the control group. Allocation concealment method: There is no concealment.
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
Research Ethics Committees of Islamic Azad University- Ardabil Branch
Street address
Basij square
City
Ardabil
Province
Ardabil
Postal code
5615731567
Approval date
2022-12-20, 1401/09/29
Ethics committee reference number
IR.IAU.ARDABIL.REC.1401.132

Health conditions studied

1

Description of health condition studied
Diabetes
ICD-10 code
L97
ICD-10 code description
Ulcer of lower limb, not elsewhere classified

Primary outcomes

1

Description
Size of diabetic foot ulcer
Timepoint
Measurement of diabetic foot ulcer at the beginning of the study and then on days 7, 14 and 28
Method of measurement
Based on the examination by specialist and the checklist taken from Fermin Digizaz's research called the scoring checklist system for the healing process of diabetic foot ulcer

2

Description
Local infection of diabetic foot ulcer
Timepoint
Investigation of wound infection at the beginning of the study and then on days 7, 14 and 28
Method of measurement
Based on the examination by specialist and the checklist taken from Fermin Digizaz's research called the scoring checklist system for the healing process of diabetic foot ulcer

3

Description
Granulation tissue formation
Timepoint
Examination of granulation tissue formation at the beginning of the study and then on days 7, 14 and 28
Method of measurement
Based on the examination by specialist and the checklist taken from Fermin Digizaz's research called the scoring checklist system for the healing process of diabetic foot ulcer

Secondary outcomes

1

Description
The duration of complete healing of diabetic foot ulcer
Timepoint
At the beginning of the study and then on days 7, 14 ,28 and 60
Method of measurement
Based on the examination of the attending physician

Intervention groups

1

Description
Intervention group: The intervention group received traditional treatment including washing twice a day with normal saline and keeping the wound clean and dry after that using the planned ointment twice a day for one month will be observed. The method of using the ointment is directly on the wound. The usual demographic information specified in the patient file is taken from the people, which includes: age, gender, occupation, education level, marital status, date and time, depth and percentage. Safety monitoring is verified by checklist in 4 stages (first day and 7, 14, 28), which includes evaluation of local and systemic side effects. Effective monitoring is done by the checklist taken from Fermin Digizaz's research called the scoring checklist system for the healing process of diabetic foot ulcers. The specialist will visit the patients to check the healing of the wound in 4 stages (the first, seventh, twenty-eighth, and sixtieth day).The presence of long-chain fats in the composition of the used fish oil keeps the wound moist and prevents the formation of scars during healing. This composition contains Eqiumrussicum plant consist of naphthoquinine and allantoin substances with the property of stimulating regeneration by rapid growth of the epidermis and mesoderm in honey base as a stimulant, antibiotic and stabilizer.
Category
Treatment - Other

2

Description
Control group: The control group received traditional treatment including washing twice a day with normal saline and keeping the wound clean and dry , and if necessary, bandaging with sterile gauze.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Velayat hospital
Full name of responsible person
Dr. Mohammad Reza Mobayen
Street address
Namjoo street
City
Rasht
Province
Guilan
Postal code
4193713194
Phone
+98 912 513 9506
Email
Maziar.mobayen@gmail.com

2

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Dr Mohammad Vakili Ojaroudi
Street address
Shahid Noeiaghdam street
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Ardabil
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khtooba۵۳@mail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr Mohammad Zaefizadeh
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Basij square
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mzaefi@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
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
Islamic Azad University
Full name of responsible person
Amin Bakhshizadeh Imcheh
Position
Medical student
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
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No.4 , Notash alley, Golmoghan bridge , Shahid barzegar street , Shohada highway
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Person responsible for scientific inquiries

Contact
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Full name of responsible person
Dr Mohammad Zaefizadeh
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Other areas of specialty/work
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Ardabil
Postal code
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Phone
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Person responsible for updating data

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Amin Bakhshizadeh Imcheh
Position
Medical student
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
Street address
No.4 , Notash alley, Golmoghan bridge , Shahid barzegar street , Shohada highway
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bakhshizadeh.dr@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

After deidentifying people, all the data obtained from the research, including the demographic information of the samples, clinical information and the results of the intervention can be shared.

When the data will become available and for how long

It is possible to access the results after nine to twelve months from the publication of the results.

To whom data/document is available

Researchers in academic centers and scientific research centers.

Under which criteria data/document could be used

In order to data comparison in similar studies, the researchers of academic centers and scientific research centers have the possibility to receive data and re-analyze it if they comply with the principles of ethics in research.

From where data/document is obtainable

Dr Mohammad Zaefizadeh with below email address: mzaefi@gmail.com and phone number +98 9144514378

What processes are involved for a request to access data/document

Researchers should send a written request to receive data to the relevant email address.A week after receiving an email , it will take action.

Comments