

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 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 Imchek

##### 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

##### **City**

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##### **Postal code**

5619647531

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khtooba03@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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## Person responsible for scientific inquiries

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Dr Mohammad Zaefizadeh  
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mzaefi@gmail.com

## Person responsible for updating data

**Contact**  
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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**  
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5616636316  
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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**