

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Evaluation of efficacy of herbal ointment containing aqueous extract Scrophularia Straita Boiss, Honey , Sativa Nigella oil ,Mazo, Apple Vinegar in treatment of ulcers diabetes

#### Protocol summary

##### Study aim

Evaluation of efficacy of herbal ointment containing aqueous extract Scrophularia Straita Boiss, Honey , Sativa Nigella oil ,Mazo, Apple Vinegar in treatment of ulcers diabetes

##### Design

This study is a clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 70 patients.

##### Settings and conduct

This study is performed in patients referred to Imam Reza Hospital and Imam Khomeini Hospital in Kermanshah. Blinding is done for all patients and clinical caregivers.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with diabetic ulcer  
Exclusion criteria: Pregnant women - Children - People undergoing chemotherapy - People receiving corticosteroids. - Patients suffering from liver and kidney failure.

##### Intervention groups

In the intervention group, wound treatment with ointment, herbal detergent and routine dressing  
In the control group, perform routine puncture and wound routine

##### Main outcome variables

Wound severity  
Wound area  
Wound site  
Wound depth  
Exodus  
Type of texture  
Pain score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201213049703N1**  
Registration date: **2021-02-10, 1399/11/22**  
Registration timing: **prospective**

Last update: **2021-02-10, 1399/11/22**

Update count: **0**

##### Registration date

2021-02-10, 1399/11/22

##### Registrant information

###### Name

Toraj Ahmadi Jouybari

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 83 3727 2049

###### Email address

t.ahmadijouybari@kums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

##### Expected recruitment start date

2021-04-04, 1400/01/15

##### Expected recruitment end date

2021-06-20, 1400/03/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of efficacy of herbal ointment containing aqueous extract Scrophularia Straita Boiss, Honey , Sativa Nigella oil ,Mazo, Apple Vinegar in treatment of ulcers diabetes

##### Public title

Effect of herbal ointment in treatment of ulcers diabetes

##### Purpose

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
Patients with diabetic ulcers

**Exclusion criteria:**  
Pregnant women Patients suffering from liver and kidney failure Children People undergoing chemotherapy People receiving corticosteroids.

**Age**  
No age limit

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**  
Target sample size: **70**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Randomization and assigning people to groups The random number function is used using Excel software as follows: First, in a column, the groups are entered as A, B and below. In the opposite column, random numbers are generated using the RAND command. In the next step, using the sort command, random numbers are generated from small to large or vice versa, which causes the order of the groups, A, B, to be changed. Using the new order, people are assigned to different groups.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
Herbal ointments and routine treatment ointments are designed to be the same in terms of color and odor so that they are not recognizable to the patient and the caregiver. And only the statistical analyst should be aware of the ointment used.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

##### Street address

Kermanshah, Shahid Beheshti Blvd., Kermanshah University of Medical Sciences

#### City

Kermanshah

#### Province

Kermanshah

#### Postal code

6715847141

#### Approval date

2020-04-11, 1399/01/23

#### Ethics committee reference number

IR.KUMS.REC.1399.073

## Health conditions studied

### 1

#### Description of health condition studied

Ulcers diabetes

#### ICD-10 code

E11.4

#### ICD-10 code description

Type 2 diabetes mellitus with neurological complications

## Primary outcomes

### 1

#### Description

PUSH Score

#### Timepoint

Every week until the 12th week

#### Method of measurement

Based on the characteristics of diabetic ulcers

## Secondary outcomes

### 1

#### Description

Wound area

#### Timepoint

Every week until the 12th week

#### Method of measurement

With a caliper, the dimensions of the wound, including the length and width of the wound, are measured and its area is calculated

### 2

#### Description

Wound depth

#### Timepoint

Every week until the 12th week

#### Method of measurement

Wound depth is measured with forceps and calipers

## Intervention groups

### 1

#### Description

The herbal ointment of the design containing thirsty

plant extract, honey, black seed oil, mazo will be provided to the patients of the intervention group in the form of ready-to-use tubes without printing of the design. Contains thirst extract, apple cider vinegar and normal saline, washed and dried with sterile gauze. The herbal ointment is then applied to the wound with a watering can and fixed with a four-layer sterile dry gauze with anti-allergy adhesive. Changing the dressing and using the ointment should be done once a day for the necessary time. (Depending on the patient's condition until complete treatment)

**Category**

Treatment - Other

**2****Description**

Liam topical ointment (manufacturer of Mehr Miracle Researchers) containing chamomile extract, 8% cow's eye, 13% beeswax and 17% honey as a routine ointment of Imam Khomeini Hospital in Kermanshah in the form of ready-to-use tubes without printing. Patients in intervention group 2 will be included. The procedure will be performed by washing the wound and surrounding tissues with normal saline solution and drying them with sterile gauze. Liam ointment is then applied to the wound with a watering can and fixed with a four-layer sterile dry gauze with anti-allergy adhesive. Changing the dressing and using the ointment should be done once a day for the necessary time. (Depending on the patient's condition until complete treatment)

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Imam khomeini Hospital

**Full name of responsible person**

Toraj Ahmadi Jouybari

**Street address**

Kermanshah -Naghlieh Ave- Imam Khomeini Hospital

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6718743161

**Phone**

+98 83 3727 2049

**Email**

dr.ahmadi\_jourbari@yahoo.co

**2****Recruitment center****Name of recruitment center**

Imam Reza Hospital

**Full name of responsible person**

Toraj Ahmadi Jouybari

**Street address**

Kermanshah -Parastar Blvd- Imam Reza Hospital

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

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**Phone**

+98 83 3427 6307

**Email**

dr.ahmadi\_jourbari@yahoo.co

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Reza KhodaRahmi

**Street address**

Shahid Beheshti Blvd, Kermanshah University of Medical Sciences

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**Email**

rkhodarahmi@mbrc.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Kermanshah 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**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Toraj Ahmadi Jouybari

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Kermanshah - Naghlieh Ave - Imam Khomeini Hospital, Kermanshah

**City**

Kermanshah

**Province**

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**Postal code**

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**Phone**

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**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Internal Medicine

**Street address**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Toraj Ahmadi Jouybari

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Kermanshah - Imam Khomeini Hospital, Kermanshah

**City**

Kermanshah

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**Postal code**

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**Phone**

+98 83 3727 2049

**Email**

dr.ahmadi\_jourbari@yahoo.com

**Person responsible for updating data****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Haji Ghorban Ghibadi

**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**

Results can be shared after not identifying people.

**When the data will become available and for how long**

Access period starts 6 months after the results are published

**To whom data/document is available**

All interested people

**Under which criteria data/document could be used**

For the use of other researchers

**From where data/document is obtainable**

Toraj Ahmadi Jouybari dr.ahmadi\_jouybari@yahoo.com

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

1. Send request to email 2. The purpose of the data request should be clear. 3. If approved by the main executor, action will be taken immediately

**Comments**