

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Evaluation of the effect of herbal supplement prepared from savory essential oil on diabetic wounds in patients with diabetic wounds

#### Protocol summary

##### Study aim

Determining the effectiveness of herbal supplement prepared from savory essential oil on diabetic wounds

##### Design

A clinical trial with a control group, with parallel, non-blind, simple randomized groups, phase 2-3 on 20 patients.

##### Settings and conduct

In Vali Asr hospital of Arak, the patient is treated for two months. Clinical trial with control group, with parallel, non-blind, simple randomized groups, phase 2-3 on 20 patients. Patients are randomly divided into two groups of 10 people. One group consists of routine care with routine treatment, and distilled water as placebo, and the second group consists of routine care with routine treatment plus savory essential oil.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Presence of diabetes mellitus, clinical findings indicating wound infection such as redness, swelling, and discharge, presence of ulcers in the extremities. Exclusion criteria: Chronic disease other than diabetes that affects wound healing, such as severe vascular disease, lupus, rheumatoid arthritis, burgers, and kidney failure.

##### Intervention groups

Rinse the wound with normal saline, spray savory essential oil on the wound with a spray, and then sterile gauze impregnated with savory essential oil is placed on the wound and bandaged. Depending on the patient's condition, this is a maximum of one or two times a day dressing of patients, and the next time a day dressing of standard treatment according to the specialized principles of treatment, wounds are bandaged. In the control group, in one of the daily dressings, after washing the wound with normal saline, it is sprayed on the wound with sterile distilled water and sprayed with sterile gas impregnated with distilled water.

##### Main outcome variables

The duration of treatment

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20161017030336N9**

Registration date: **2022-01-23, 1400/11/03**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-01-23, 1400/11/03**

Update count: **0**

##### Registration date

2022-01-23, 1400/11/03

##### Registrant information

##### Name

Ghasem Habibi

##### Name of organization / entity

Islamic azad university

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3367 3208

##### Email address

dr.habibi@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-01-21, 1400/11/01

##### Expected recruitment end date

2022-03-21, 1401/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Evaluation of the effect of herbal supplement prepared from savory essential oil on diabetic wounds in patients with diabetic wounds

## Public title

The effect of savory essential oil on diabetic wounds

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Proven diabetes  
Clinical findings that indicate wound infection such as redness, swelling, and discharge  
Presence of ulcers in the extremities of patients  
Having a body mass index of 18 to 35  
Having full consciousness upon entering the study

### Exclusion criteria:

Drug and alcohol abuse  
Having a chronic disease other than diabetes that affects the healing process of wounds such as severe vascular disease, lupus, rheumatoid arthritis, burgers and kidney failure  
Consumption of immunosuppressants  
Cancer and the use of cytotoxic drugs

## Age

From **14 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **20**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Due to the fact that this plan is not blind, the control and intervention groups are selected by simple random method, so that patients are numbered in the order of admission to the hospital in numbers from one to twenty, the first 10 admitted group We consider the intervention and the second 10 admitted people are considered as the control group.

## 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 Islamic Azad University, Arak Branch

#### Street address

Imam Khomeini Square, Imam Khomeini Boulevard, 3 km of Khomeini Road, Amirkabir University Town

#### City

Arak

#### Province

Markazi

#### Postal code

3836119131

#### Approval date

2022-01-07, 1400/10/17

#### Ethics committee reference number

IR.IAU.ARAK.REC.1400.040

## Health conditions studied

### 1

#### Description of health condition studied

Unspecified diabetes mellitus with peripheral circulatory complications

#### ICD-10 code

E10

#### ICD-10 code description

Type 1 diabetes mellitus

### 2

#### Description of health condition studied

Wound complication

#### ICD-10 code

T81.3

#### ICD-10 code description

Disruption of wound, not elsewhere classified

## Primary outcomes

### 1

#### Description

Degree of diabetic foot ulcer

#### Timepoint

Before the intervention and every week for up to four weeks after the intervention

#### Method of measurement

The degree and depth of diabetic wounds in centimeters in both control and test groups are assessed by the researcher

### 2

#### Description

Duration of treatment

#### Timepoint

Before the intervention and every week for up to four weeks after the intervention

#### Method of measurement

The degree and depth of diabetic wounds in centimeters in both control and test groups are assessed by the researcher

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Washing the wound with normal saline, spraying safflower essential oil on the wound with a spray, and then sterile gauze impregnated with safflower essential oil is placed on the wound and bandaged. Depending on the patient's condition, this is a maximum of one or two times a day dressing of patients and the next time a day dressing of standard treatment according to the specialized principles of treatment, wounds are bandaged

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Rinse the wound with normal saline, spray sterile distilled water on the wound with a sprayer, and then sterile gauze soaked in sterile distilled water is placed on the wound and bandaged. Depending on the patient's condition, this is a once-daily dressing of the patients, and the next time the dressing is applied from the standard treatment according to the specialized principles of treatment, the wounds are bandaged.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Vali Asr Hospital, Arak

##### Full name of responsible person

Dr.Saeed Heidari

##### Street address

Valiasr Square, Valiasr Hospital

##### City

Arak

##### Province

Markazi

##### Postal code

3814957558

##### Phone

+98 86 3222 2003

##### Fax

+98 86 3223 1283

##### Email

heidari\_65@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Farane Zar Afshan

##### Street address

Arak - Imam Khomeini Square - Imam Khomeini Boulevard - 3 km of Khomeini Road - Amirkabir University Town - Vice Chancellor for Research and Technology, Center for Growth and Technology

##### City

Arak

##### Province

Markazi

##### Postal code

3836119131

##### Phone

+98 86 3341 2101

##### Email

fzarafshan@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

Ghasem Habibi

##### Position

Research Assistant

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Traditional Medicine

##### Street address

Arak - Imam Khomeini Square - Imam Khomeini Boulevard - 3 km of Khomeini Road - Amirkabir University Town Growth and Technology Center

##### City

Arak

##### Province

Markazi

##### Postal code

3836119131

**Phone**

+98 86 3341 2101

**Email**

ghasemhabibi.chem@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Fateme Bandarian

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

General Practitioner

**Street address**

North Kargar St., Shahrivar St., corner of Hiyat St.,  
Diabetes Clinic, Floor 5, Diabetes Research Center

**City**

Tehran

**Province**

Tehran

**Postal code**

1441716411

**Phone**

+98 21 8833 8742

**Email**

fbandarian@yahoo.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Ghasem Habibi

**Position**

Research Assistant

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Traditional Medicine

**Street address**

Arak - Imam Khomeini Square - Imam Khomeini  
Boulevard - 3 km of Khomeini Road - Amirkabir  
University Town Growth and Technology Center

**City**

Arak

**Province**

Markazi

**Postal code**

3836119131

**Phone**

+98 86 3341 2101

**Email**

ghasemhabibi.chem@gmail.com

**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**

Not applicable

**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**

Not applicable

**Data Dictionary**

Not applicable