

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Clinical trial to evaluate the effect of Myrtus extract on healing of diabetic foot wounds

#### Protocol summary

##### Summary

The objectives of this clinical trial are to evaluate the effect of herbal extract of Myrtus on healing of diabetic foot ulcers. In the first step effect of the extract will evaluate on the skin of 5 healthy people. Study groups: due the infectious nature of study, outpatients and inpatients of ValiAsr hospital will enter to the study. Sample size: A total of 70 diabetic patients with diabetic foot ulcers will be admitted with obtaining informed consent. In this not blinded study, patients will be randomly divided into two groups of control (n = 35) and intervention (n = 35). Major eligibility criteria of participants: proven diabetes, ulcers on toes, foot, heel, top of toe, having a body mass index of 18 to 35; complete consciousness, age 20 to 80. Exclusion criteria: drug and alcohol abuse, chronic disease effective on diabetic wound healing, any immunosuppressive and cytotoxic drugs user, cancer, amputation case. For both groups, the standard treatment will be performed. For the test group, in addition to standard therapy, herbal extract will use. Grid and depth of diabetic foot ulcers in both control and experimental groups before and after the intervention will be assessed by the investigator according to the University of Texas wound classification system. Primary outcome time point will be measured before the intervention and every weeks up to four weeks after the intervention.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016020626394N1**  
Registration date: **2016-08-23, 1395/06/02**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-08-23, 1395/06/02

##### Registrant information

###### Name

Mohammad Arjomandzadegan

###### Name of organization / entity

Arak University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 3417 3505

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##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Arak University of Medical Sciences

##### Expected recruitment start date

2016-02-20, 1394/12/01

##### Expected recruitment end date

2016-07-20, 1395/04/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Clinical trial to evaluate the effect of Myrtus extract on healing of diabetic foot wounds

##### Public title

Study of Effect of Myrtus extract on diabetic foot wounds

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Proved diabetes; clinical findings

indicative for wound infection (redness, swelling and discharge; diabetic foot wound), wounds on toes; foot, the heel and top of the toe; body mass index 18 to 35; full consciousness, age 20 to 80 years. The exclusion criteria: drugs and alcohol abuse; chronic disease other than diabetes affects the healing process of wounds such as severe vascular disease, lupus, rheumatoid arthritis, burgers and kidney failure; Immunosuppressive and cytotoxic drug users.

#### **Age**

From **20 years** old to **80 years** old

#### **Gender**

Both

#### **Phase**

2-3

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **70**

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

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Not blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

Restricted randomization

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Arak University of Medical Sciences

##### **Street address**

Pardis of Arak University of Medical Sciences, Basidj Bridge, Sadasht, Arak, IR. IRAN

##### **City**

Arak

##### **Postal code**

#### **Approval date**

2016-01-26, 1394/11/06

#### **Ethics committee reference number**

IR.ARAKMU.REC.1394.257

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Diabetic Foot Ulcers

#### **ICD-10 code**

E10

#### **ICD-10 code description**

diabetes, With peripheral circulatory complications

## **Primary outcomes**

### **1**

#### **Description**

Grade of diabetic foot ulcers

#### **Timepoint**

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

#### **Method of measurement**

Grade and depth of diabetic foot ulcers in both control and experimental groups before the intervention, according to the University of Texas wound classification system will be assessed by the investigator.

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention group: standard treatment for diabetic foot ulcers will accomplish based on infection control, pressure and if necessary debridement of necrotic tissue. Oral antibiotic therapy appropriate to the condition of patient will admit and wound cleaning with normal saline will perform. In addition herbal extracts will use as wound washing with normal saline, spray of the extract with insulin syringe on the wound, gauze embedded with the extract will put on the wound and will be tied. This will perform 2 to 4 times depending on the patient's condition. Treatment by extract will be increased in cases with more severe lesions or toes will float in the extract for about 15 minutes if necessary, according to depth of the wound.

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

Control group: Standard treatment for diabetic foot ulcers will accomplish based on infection control, pressure removal and if necessary debridement of necrotic tissue. Oral antibiotic therapy appropriate to the condition of patient will admit and wound cleaning with normal saline will perform.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

## 1

### Recruitment center

**Name of recruitment center**

Arak University of Medical Sciences, Vali-Asr Hospital

**Full name of responsible person**

Dr. Farshideh Didgar

**Street address**

Medicine Faculty, Arak University of Medical Sciences,  
department of Infectious Diseases

**City**

Arak

## Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Vice chancellor for research, Arak University of  
Medical Sciences

**Full name of responsible person**

Arak University of Medical Sciences, Vice chancellor  
for research, Dr Mohammad Rafiee

**Street address**

Pardis of Arak University of Medical Sciences,  
Sardasht, Basidj Bidge, Arak, IR. IRAN

**City**

Arak

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

Yes

**Title of funding source**

Vice chancellor for research, Arak University of Medical  
Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Infectious Diseases Research Center

**Full name of responsible person**

Ghasem Habibi Dehfooli

**Position**

Research Assistant

**Other areas of specialty/work****Street address**

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## Person responsible for scientific inquiries

### Contact

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Dr. Mohammad Arjomandzadegan

**Position**

Associate Professor

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*  
**Statistical Analysis Plan**  
*empty*  
**Informed Consent Form**  
*empty*  
**Clinical Study Report**

*empty*  
**Analytic Code**  
*empty*  
**Data Dictionary**  
*empty*