

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Study of Thyme essential oil effect on infection control of diabetic foot ulcers

#### Protocol summary

##### Summary

The objectives of this clinical trial are to evaluate the effect of herbal essential oil of Thyme on infection control of diabetic foot ulcers. Study groups: due the infectious nature of study, outpatients and inpatients of ValiAsr hospital will enter to the study. Sample size: A total of 60 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 = 30) and intervention (n = 30). 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, diluted essential oil 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. Primary outcome time point will be measured before the intervention and every week up to four weeks after the intervention.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017011026394N2**  
Registration date: **2017-02-10, 1395/11/22**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-02-10, 1395/11/22

#### Registrant information

##### Name

Mohammad Arjomandzadegan

##### Name of organization / entity

Arak University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

arjomandzadegan@arakmu.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice chancellor for research, Arak University of Medical Sciences

#### Expected recruitment start date

2017-02-09, 1395/11/21

#### Expected recruitment end date

2017-12-01, 1396/09/10

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Study of Thyme essential oil effect on infection control of diabetic foot ulcers

#### Public title

Study of Thyme essential oil effect on infection control of diabetic foot ulcers

#### 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: **60**

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

Randomized

#### **Randomization description**

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

Not blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Single

#### **Other design features**

randomized grouping to control and intervention groups

## **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**

3819693345

#### **Approval date**

2016-09-14, 1395/06/24

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

IR.ARAKMU.REC.1395.268

## **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 as centimeters in both control and experimental groups before the intervention, will be assessed by the investigator.

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

In addition to standard treatment for diabetic foot ulcers as control group, diluted Thyme essential oil will use for wound treatment as spray of Diluted Thyme essential oil with insulin syringe on the wound, gauze embedded with the solution will put on the wound, if needed. This will perform 2 to 4 times per day depending on the patient's condition.

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

Control 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.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

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

##### **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**

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

**Full name of responsible person**

Dr Mohammad Rafiee

**Street address**

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

**City**

Arak

**Grant name**

**Grant code / Reference number**

2691

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

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

**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**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**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*