

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

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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

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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

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Sardasht, Basidj Bidge, Arak, IR. IRAN

City

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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

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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