

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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