

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jun 2026

Evaluation of Antiperspirant effect of leaf extract of *Myrtus communis* L. in healthy volunteers: a double-blind randomized clinical trial

Protocol summary

Study aim

Determining the antiperspirant effect of the *Myrtus Communis* L.

Design

A clinical trial with a control group, with cross-over groups, double-blind, randomized, phase 3 on 20 volunteers, random block allocation method was used for randomization.

Settings and conduct

This project was carried out in the Faculty of Pharmacy in Yazd. Volunteers are randomly assigned to two groups, A and B, and use the product for one week, and after a two-week washout period, they are assigned to the opposite group.

Participants/Inclusion and exclusion criteria

Volunteers between the ages of 18 and 65 who do not use any other antiperspirant drugs or products. After obtaining informed consent, they entered the study. Exclusion criteria are: if serious side effects occur, menopause, pregnancy, overweight and obesity, thyroid disorders.

Intervention groups

Volunteers use a 2% spray of the *Myrtus communis* L extract (made in Yazd Pharmacy Faculty) for 7 days and 2 times a day in the axillary area. Control group: Volunteers use placebo spray (made in Yazd Pharmacy Faculty) for 7 days and 2 times a day in the axillary area.

Main outcome variables

Sweat intensity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181208041882N17**

Registration date: **2023-10-29, 1402/08/07**

Registration timing: **retrospective**

Last update: **2023-10-29, 1402/08/07**

Update count: **0**

Registration date

2023-10-29, 1402/08/07

Registrant information

Name

behrooz heydari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3820 8699

Email address

b.heydari@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2023-07-22, 1402/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Antiperspirant effect of leaf extract of *Myrtus communis* L. in healthy volunteers: a double-blind randomized clinical trial

Public title

Antiperspirant effect of leaf extract of *Myrtuscommunis* L.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Informed consent Volunteers who do not take any other antiperspirant medications or products. Volunteers between the ages of 18 and 65

Exclusion criteria:

If serious side effects occur Menopause Pregnancy Overweight and obesity Thyroid disorders

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 20 participants are randomly and periodically placed in one of two groups (A and B). In order to randomize, the block random allocation method was used. In this study, 4 blocks of 5 were considered. The permutations produced include the letters A and B are repeated. These permutations were produced with the help of Random allocation software version 1. For this purpose, the list prepared by the software is from number 1 to 20, which are placed in 4 blocks of five. The implementation of this software output will give the first qualified person number 1 and the last person will receive number 20.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients, the physician, and the assessor of clinical symptoms will be all blinded to the intervention's assignments during performing the study. In this way, the first executor of the sequence plan determines the allocation of individuals according to the order in which patients enter the study and puts The formulation contains the Myrtus communis L extract and placebo (the same in terms of color, smell, and shape) in the same shape boxes for patient consumption. And identifies them with codes A or B. The student then delivers the appropriate medications to the patients.

Placebo

Used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

School of Medicine- Shahid Sadoughi University of Medical Sciences

Street address

Shahid Sadoughi University of Medical Science, Shohadaye Gomnam Blvd, Alem Sq

City

Yazd

Province

Yazd

Postal code

8915173143

Approval date

2019-05-19, 1398/02/29

Ethics committee reference number

IR.SSU.MEDICINE.REC.1398.079

Health conditions studied**1****Description of health condition studied**

Sweating

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

The amount of perspiration

Timepoint

week 0 and 1

Method of measurement

Visual analog scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Volunteers use a 2% spray of the Myrtus communis L extract (made in Yazd Pharmacy Faculty) for 7 days and 2 times a day in the axillary area.

Category

Treatment - Drugs

2**Description**

Control group: Volunteers use placebo spray (made in Yazd Pharmacy Faculty) for 7 days and 2 times a day in

the axillary area.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Yazd Faculty of Pharmac

Full name of responsible person

Behrooz Heydari

Street address

Shahid Sadoughi University of Medical Sciences,
Shohadaye Gomnam Blvd, Alem Sq

City

Yazd

Province

Yazd

Postal code

8915173143

Phone

+98 35 3820 3410

Email

b.heydari@ssu.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Amin Salehi Abarghouei

Street address

Shahid Sadoughi University of medical sciences,
Shohadaye Gomnan Blvd, Alem Sq

City

Yazd

Province

Yazd

Postal code

8915173149

Phone

+98 35 3146 2150

Email

abargouei@ssu.ac.ir

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

Yes

Title of funding source

Yazd University of Medical Sciences

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**

Yazd University of Medical Sciences

Full name of responsible person

Behrooz Heydari

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Shahid Sadoughi University of Medical Sciences,
Shohadaye Gomnam Blvd, Alem Sq

City

Yazd

Province

Yazd

Postal code

8915173143

Phone

+98 35 3820 3410

Email

b.heydari@ssu.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Behrooz Heydari

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Shahid Sadoughi University of medical sciences,
Shohadaye Gomnan Blvd, Alem Sq

City

Yazd

Province

Yazd

Postal code

8915173143

Phone

+98 35 3820 3410

Email

b.heydari@ssu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Behrooz Heydari

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Shahid Sadoughi University of medical sciences,
Shohadaye Gornam Blvd, Alem Sq

City

Yazd

Province

Yazd

Postal code

8915173143

Phone

+98 35 3820 3410

Email

b.heydari@ssu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

After nonrecognition, all data can be share

When the data will become available and for how long

6 months after publication

To whom data/document is available

All of researchers

Under which criteria data/document could be used

Nothing

From where data/document is obtainable

Behrooz Heydari email: b.heydari@ssu.ac.ir

What processes are involved for a request to access data/document

Request your information by email. The data will be sent after a week.

Comments