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 Gomnam 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