

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The effect of viola odorata syrup on hot flashes and sleep quality in postmenopausal women

Protocol summary

Study aim

Determining the effect of violet syrup on hot flashes and sleep quality in postmenopausal women.

Design

Clinical trial with control group, with parallel groups, triple blind, randomized

Settings and conduct

Mashhad Health Centers

Participants/Inclusion and exclusion criteria

At least the reading and writing skills; postmenopausal patient; experience at least 3 hot flashes throughout the day; having a sleep quality score higher than 5; age 40 to 65 years old; no smoking and alcohol; lack of hormone therapy in the last 6 months; not having depression, stress, or severe anxiety; not having physical illness; lack of mental illness; non-infectious and febrile illness; lack of simultaneous use of hypnotic and herbal medicines affecting sleep and hot flashes; do not take medications that improve vasomotor symptoms; non-use of anti-coagulants, anxiolytic and non-steroidal drugs; not having a night shift; non-use of isoflavone absorption reducing agents during the study, such as antibiotics for 6 weeks, and proton pump inhibitor anti-acids.

Intervention groups

In the intervention group, vials of violet syrup were used and in the control group, placebo was used.

Main outcome variables

Flushing and sleep quality

General information

Reason for update

Changed sampling date that was incorrectly recorded

Acronym

IRCT registration information

IRCT registration number: **IRCT20180514039660N1**

Registration date: **2018-08-07, 1397/05/16**

Registration timing: **prospective**

Last update: **2022-04-20, 1401/01/31**

Update count: **2**

Registration date

2018-08-07, 1397/05/16

Registrant information

Name

Fatemeh Lotfi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3842 2696

Email address

lotfif951@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

2018-08-23, 1397/06/01

Actual recruitment end date

2019-04-30, 1398/02/10

Trial completion date

2019-04-30, 1398/02/10

Scientific title

The effect of viola odorata syrup on hot flashes and sleep quality in postmenopausal women

Public title

The effect of viola odorata syrup on hot flashes and sleep quality in postmenopausal women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

At least the reading and writing skills Post-menopausal (at least 12 months of self-deprivation of menstruation, without contact with pregnancy and lactation, or other medical and pharmaceutical reasons or serum FSH > 40 IU / L). Experience at least 3 hot flashes throughout the day Having a sleep quality score higher than 5 Age 40 to 65 years old

Exclusion criteria:

Tobacco and alcohol consumption Hormone therapy in the last 6 months Having depression, stress or severe anxiety (score less than 19 below the stress scale, score less than 10 below the anxiety scale or score less than 14 below the depression scale of the DASS-21 questionnaire) Having physical illnesses (such as diabetes, hypertension, pulmonary, heart, infectious diseases, cancers) Mental illness Infectious and febrile illnesses (such as respiratory, urinary and hepatitis infections, thyroid disease, and those with hot flush as one of their symptoms). Concomitant use of hypnotic and herbal medicines affecting sleep and hot flashes (such as soy and herbs) Taking medications that improve vasomotor symptoms (such as clonidine, antidepressants, tamoxifen, raloxifene, anticonvulsants like gabapentin) Use of anti-coagulants, anti-anxiety and non-steroidal drugs Having a night shift The use of isoflavone absorption inhibitors during the study, such as antibiotics for 6 weeks, and proton pump inhibitors (omeprazole, lansoprazole, ropiperazole, pantoprazole, omeprazole)

Age

From **40 years** old to **65 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **94**

Actual sample size reached: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Firstly, from the 5th and Samen areas of the city of Mashhad, the names of all these centers are written on paper and selected through the drawings of two centers, then from the sub-set of the two centers, each of which has two centers suitable for personnel cooperation and the presence of The menopause women will be selected and the researcher will be present at each of these centers and selected on the basis of the checklist for the selection of the research unit, eligible women to enter the study are available. Then the violet flower syrup from Barij and Placebo, the researcher will be provided by the pharmacist's consultant in similar glasses. Each glass has a code chosen by the random number table, and only the pharmacist's consultant knows. Individuals with entry requirements are assigned code numbers in groups

respectively.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In order to blind the violet flower syrup from Barij and Placebo, the researcher will be provided by the pharmacist's consultant in similar glasses. Each glass has a code chosen by the random number table, and only the pharmacist's consultant knows. Individuals with entry requirements are assigned code numbers in groups respectively. Therefore, until the end of the study, the research units, researcher and statistician will not be aware of the codes related to violet syrup and placebo.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

School of Nursing and Midwifery, Mashhad University of Medical Sciences

Street address

Faculty of Nursing and Midwifery, Doctora Crossroads, Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2018-05-29, 1397/03/08

Ethics committee reference number

IR.MUMS.NURSE.REC.1397.005

Health conditions studied

1

Description of health condition studied

Hot flashes

ICD-10 code

N95.1

ICD-10 code description

Menopausal and female climacteric states

2

Description of health condition studied

sleep disorders

ICD-10 code

G47

ICD-10 code description

Sleep disorders

Primary outcomes

1

Description

Hot flashes

Timepoint

From a week before the study begins to immediately after the intervention

Method of measurement

Hot flashes daily registration form

2

Description

Sleep quality

Timepoint

Before starting the study until immediately after the intervention

Method of measurement

Pittsburg Sleep Quality Index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Violet Flower Syrup from Barís Essence, every 5 ml of flavonoid containing syrup is 16.25-9 mg. The units are taking 5 ml every other day for one month each two times a day.

Category

Treatment - Other

2

Description

Control group: Use of placebo in similar glasses of syrup; the units are taking 5 ml every other day for one month each two times a day.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Samen Health Center

Full name of responsible person

Dr. Mohammad Mehdi Izadpanah

Street address

Akhund Khorasani 24, Gonbad Sabz Square

City

Mashhad

Province

Razavi Khorasan

Postal code

9135963114

Phone

+98 51 3852 6761

Email

lotfif951@mums.ac.ir

2

Recruitment center

Name of recruitment center

Health center of Hazrat Zahra S.

Full name of responsible person

Brattali Arab Nejad

Street address

Hasheminejad 14, Hasheminejad Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9185837715

Phone

+98 51 3222 9289

Email

lotfif951@mums.ac.ir

3

Recruitment center

Name of recruitment center

Shahid Ghodsi Health Center

Full name of responsible person

Brattali Arab Nejad

Street address

Next to the blood bank, The end of Sanabad Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9185837715

Phone

+98 51 3845 1552

Email

lotfif951@mums.ac.ir

4

Recruitment center

Name of recruitment center

Silo Health Center

Full name of responsible person

Brattali Arab Nejad

Street address

16th Resalat, Resalat Avenue

City

Mashhad

Province

Razavi Khorasan

Postal code
9185837715
Phone
+98 51 3274 5585
Email
lotfif951@mums.ac.ir

Faculty of Nursing and Midwifery, Doctora Crossroads,
Daneshgah Street

City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3859 1511
Email
lotfif951@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mohammad Reza Darabi Mahboob
Street address
Faculty of Nursing and Midwifery, Doctora Crossroads,
Daneshgah Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3859 1511
Email
lotfif951@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Fatemeh Lotfi
Position
student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Fatemeh Zahra Karimi
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Faculty of Nursing and Midwifery, Doctora Crossroads,
Daneshgah Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3859 1511
Email
Karimifz@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Fatemeh Lotfi
Position
student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Faculty of Nursing and Midwifery, Doctora Crossroads,
Daneshgah Street
City
Mashhad
Province
Razavi Khorasan
Postal code

9137913199

Phone

+98 51 3859 1511

Email

lotfif951@mums.ac.ir

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available