Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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
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Iran (Islamic Republic of)
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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, osomoperazole)

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 forone 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 forone 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
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2

Recruitment center
Name of recruitment center
Health center of Hazrat Zahra S.
Full name of responsible person
Brattali Arab Nejad
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Hasheminejad 14, Hasheminejad Street
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3

Recruitment center
Name of recruitment center
Shahid Ghodsi Health Center
Full name of responsible person
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4

Recruitment center
Name of recruitment center
Silo Health Center
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
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
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Person responsible for updating data

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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