

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

comparative study of the effect of capsule containing Vitex agnus castus extract with nigella sativa powder in comparison with citalopram in reducing hot flashes in postmenopausal women

Protocol summary

Study aim

Investigating effect of capsules containing extract of Vitex agnus castus and Nigella Sativa powder and extract in comparison with citalopram

Design

In this research, 46 eligible menopausal patients referring to medical centers of golestan medical university were chosen purposefully and were randomly divided into two groups of control and intervention. Group allocation was concealed by assigning a unique code to each participants.

Settings and conduct

In this intervention study ,which is a randomized double blinded clinical trial,46 postmenopausal women who visit the Mohab YAS Hospital are examined.At the first meeting after taking the history and complete examination ,including a breast examination and,if necessary, ultrasonography, mammography and vaginal examination , and in absence of pap smear in the last six month ,smear and obtaining written consent , and in the case of normal clinical trial,the relevant questionnaires will be completed for them.The research methodology will be based on the goal.Randomly one of the two groups receiving the 20mg Citalopram tablet and the capsule containing Nigella Sativa powder and Vitex agnus castus extract ,1mg daily after breakfast,and other group receiving 20mg of Citalopram and placebo ,for eight weeks each day and for two month ,the drugs are prescribed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having hot flash symptoms, satisfaction to participate in the study, passing at least one year from menstruation after the onset of menopause Exclusion criteria: sensitivity to the studied plants ,the emergence of any mental illness,increased symptoms of hot flashes

Intervention groups

1- Control group: receiving 20 mg citalopram together with placebo for eight weeks. 2- Intervention group: receiving 20 mg citalopram together with capsules containing 1g Nigella Sativa powder and Vitex agnus castus extract for eight weeks

Main outcome variables

examining rate of flushing and sweating in menopausal women

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170220032695N2**

Registration date: **2018-01-26, 1396/11/06**

Registration timing: **retrospective**

Last update: **2018-01-26, 1396/11/06**

Update count: **0**

Registration date

2018-01-26, 1396/11/06

Registrant information

Name

shima afshar

Name of organization / entity

golestan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 17 3222 7721

Email address

dr.afshar@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-07, 1396/07/15

Expected recruitment end date

2017-12-22, 1396/10/01

Actual recruitment start date

2017-10-07, 1396/07/15

Actual recruitment end date

2017-12-22, 1396/10/01

Trial completion date

empty

Scientific title

comparative study of the effect of capsule containing Vitex agnus castus extract with nigella sativa powder in comparison with citalopram in reducing hot flashes in postmenopausal women

Public title

effect of capsule containing vitex agnus castus extract with Nigella sativa powder on reducing hot flashes

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having hot flash symptoms, , satisfaction to participate in the study passing at least one year from menstruation after the onset of menopause

Exclusion criteria:

sensitivity to the studied plants the emergence of any mental illness increased symptoms of hot flashes

AgeFrom **45 years** old to **60 years** old**Gender**

Female

Phase

N/A

Groups that have been masked

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

Sample sizeTarget sample size: **46**Actual sample size reached: **46****Randomization (investigator's opinion)**

N/A

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

Absence of knowledge of the participants and the clinical care observant of the drug or placebo capsule

Placebo

Used

Assignment

Crossover

Other design features**Secondary Ids**

empty

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

ethics committee of Islamic Azad University of medical science

Street address

Yasaman Ave., Shariati Ave.

City

Tehran

Province

Tehran

Postal code

6466-19395

Approval date

2016-10-24, 1395/08/03

Ethics committee reference number

IR.IAU.PS.REC.1395.26

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

flushing

ICD-10 code

R23.2

ICD-10 code description

Flushing

Primary outcomes**1****Description**

flushing questionnaire score

Timepoint

immediately before initiation of intervention, one month and two months after intervention

Method of measurement

questionnaire score

Secondary outcomes

empty

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

capsules containing one gram Vitex agnus castus extract and nigella sativa powder

Category

Treatment - Drugs

2

Description

1 gram capsule containing plasebo after break fast

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

medical centers of Golestan university of medical science

Full name of responsible person

Mahboube Shirazi

Street address

tehran Medical of university sciences, 16 azar street

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 81631

Email

mahboobeh.shirazi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

GholamReza Amin

Street address

No. 1831, floor 4, north kargar street

City

Tehran

Province

Tehran

Postal code

1416883834

Phone

+98 21 8802 4411

Email

Amin@tums.ac.ir

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

Tehran University of Medical sciences

Full name of responsible person

gholamreza amin

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Tehran University of Medical sciences, enghelab street

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 218802441

Fax

Email

amin@tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical sciences

Full name of responsible person

Gholamreza amin

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Tehran University of Medical sciences, 16 Azar Street

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 81631

Fax

Email
amin@tums.ac.ir
Web page address

193956466
Phone
+98 21 2200 6221
Fax
Email
afshar.shiima@gmail.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Shima Afshar
Position
Pharm D
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
Islamic azad University of Pharmaceutical
Sciences,Yasaman Street.Shariati Street
City
Tehran
Province
Tehran
Postal code

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

no data

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available