Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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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
Age
From **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 size
Target 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 sience
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
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1417653761
Phone
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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
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1416883834
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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
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Person responsible for updating data

Contact
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Islamic Azad University
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Shima Afshar
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Pharm D
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
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Islamic azad University of Pharmaceutical Sciences,Yasaman Street.Shariati Street
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193956466
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+98 21 2200 6221
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afshar.shiima@gmail.com
Web page address

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