Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jan 2020

Effec of Black cohosh on early symptoms of menopause

Protocol summary

Summary

The aim of this randomized controlled trial (double blind) is to determine the effect of Black cohosh on the early symptoms of menopause. We will recruit 84 cases of post menopausal women 45-60 years old at selected health care centers in Tehran/Iran.After getting written informed consent, participants will complete the demographic charactristics.Then we will randomly allocate them into intervention and control groups using permuted block randomization with block sizes of four and six concealed in sequentially numbered, sealed, opaque envelopes. Participants will be asked to note number of daily flushing for 1 week and then will be given capped envelopes containing 56 tablets (Black cohosh or placebo) with the order of 1 tablet daily after dinner.participants will complete Green scale 4 and 8 weeks after intervention , at the same time the participants will give tab of the record number of flushing or possible side effects based on the checklist to the researcher.The research assistant (assessor) wil be blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107186709N4**
Registration date: **2012-01-15, 1390/10/25**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-01-15, 1390/10/25

Registrant information

Name

Mahnaz Shahnazi

Name of organization / entity

Tabriz University of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research Deputy of Tabriz University of Medical Sciences

Expected recruitment start date

2012-01-21, 1390/11/01

Expected recruitment end date

2012-07-22, 1391/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effec of Black cohosh on early symptoms of menopause

Public title

Effect of Black cohosh(Cimi fugol) on early symptoms of menopause

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The age range is 45 to 60 years; During the past 12 months have not been menstural periods; With minimum score of 15 to maximum of 42 in Green score; Absence of disease or a history of breast cancer, uterine cancer, abnormal vaginal bleeding, liver disease, depression or hyperthyroidism (which must be approved by the medical center physician); have normal blood pressure(100/60 to 140/90); N0 use of hormonal or herbal drugs for relief of menopausal symptoms or other neurological drugs in the 2 past months or during the study; The lack of sensitivity to spices or essences; No-smoking and do not drinking alcohol. Exclusion criteria: medical complications during the study

Age

From **45 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **84**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Deputy of Tabriz University of Medical Sciences
Street address
Golgasht street, Tabriz
City
Tabriz
Postal code
51665-118
Approval date
2011-12-19, 1390/09/28
Ethics committee reference number
9061

Health conditions studied

1

Description of health condition studied
Early symptoms of menopause
ICD-10 code
N95.1
ICD-10 code description
Menopausal and female climactric states

Primary outcomes

1

Description
Vasomotor symptoms
Timepoint
One week befor and 4 and 8 weeks after intervention
Method of measurement
Green scale

2

Description
Psycological symptoms
Timepoint
One week befor and 4 and 8 weeks after intervention
Method of measurement
Green scale

3

Description
Added at 2013-06-01:Final Green score.
Timepoint
Added at 2013-06-01: 4 & 8 weeks later after intervention
Method of measurement
Added at 2013-06-01: l Green score.

Secondary outcomes

1

Description
Physical symptoms
Timepoint
One week befor and 4 and 8 weeks after intervention
Method of measurement
Green scale

Intervention groups

1

Description
Intervention group:They will use oral tablet Cimi fugol daily for 8 weeks ,one tablet after dinner .
Category
Treatment - Drugs

2

Description
Control group:The placebo are tablets which will prepare like as Cimi fugol (shape and size) without effective drugs that will be given to participants with order of 1 tablet after dinner.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Sardar jangle
Full name of responsible person
Nahaee Jila
Street address
Ordibehesht Ave, Sardar jangle
City
Tehran

2

Recruitment center
Name of recruitment center
Sahid Ghaffary
Full name of responsible person
Nahaee Jila
Street address
Phase 2, Ekbatan
City
Tehran

3

Recruitment center
Name of recruitment center
Kan
Full name of responsible person
Nahaee Jila
Street address
Shahid Afkhami Ave, Shahre ziba
City
Tehran

4

Recruitment center
Name of recruitment center
Fazel
Full name of responsible person
Nahaee Jila
Street address
Dehkade Ave, Keshavarz Blv
City
Tehran

5

Recruitment center
Name of recruitment center
Share ziba
Full name of responsible person
Nahaee Jila
Street address
No.11, Shahran
City
Tehran

6

Recruitment center
Name of recruitment center
Farahzad
Full name of responsible person
Nahaee Jila
Street address
Eisar Ave, Farahfzad Blv
City
Tehran

7

Recruitment center
Name of recruitment center
Shahid Fakoory
Full name of responsible person
Nahaee Jila
Street address
Special road of Karaj
City
Tehran

8

Recruitment center
Name of recruitment center
Roudehen health care center
Full name of responsible person
Nahaee Jila
Street address
Emam Khomeini Blv, Roudehen
City
Damavand

9

Recruitment center
Name of recruitment center
Jilard health care center
Full name of responsible person
Nahaee Jila
Street address
Helale Ahmar Ave, Jilard
City
Damavand

10

Recruitment center
Name of recruitment center
Kilan health care center
Full name of responsible person
Nahaee Jila
Street address
Shahid Beheshti Ave, Taleghani Square, Kilan
City
Damavand

11

Recruitment center
Name of recruitment center
Abesard health care center
Full name of responsible person
Nahaee Jila
Street address
Shahid Fahmide Ave, Emam Khomeini square, Abesard
City
Damavand

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Deputy of Tabriz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Reza Rashidi
Street address
Golgashat Street, Tabriz
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Deputy of Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Person responsible for scientific inquiries

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Person responsible for updating data

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jnahaee@yahoo.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty