

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jan 2020

Effect 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 characteristics. 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) will 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

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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

Effect 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 menstrual 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); NO 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 climactic states

Primary outcomes

1

Description

Vasomotor symptoms

Timepoint

One week before and 4 and 8 weeks after intervention

Method of measurement

Green scale

2

Description

Psychological symptoms

Timepoint

One week before 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: I Green score.

Secondary outcomes

1

Description

Physical symptoms

Timepoint

One week before 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, Shahrhan

City

Tehran

6**Recruitment center****Name of recruitment center**

Farahzad

Full name of responsible person

Nahaee Jila

Street address

Eisar Ave, Farahzad 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

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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

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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**

Tabriz University of Medical Sciences

Full name of responsible person

Nahaee Jila

Position

Master of sciences student in midwifery

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Full name of responsible person

Shahnazi Mahnaz

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

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Position

Master of sciences student in midwifery

Other areas of specialty/work**Street address**

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City

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Postal code**Phone**

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Fax**Email**

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