

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Comparative investigate the effect of black cohosh (simifugol) and vitexagnus _castus(agnugol) on menopausal symptoms

Protocol summary

Summary

The aim of this study isto compare the effect of black cohosh (simifugol) and vitex agnus castus(agnugol) on menopausal symptoms in menopause women referring to Rafsanjan health care centers in 2016. . Research population includes menopausal women between 45 to 65 years old who acquire at least 5 score of Menopause Rating Scale (MRS)questionnaire and have other inclusion criteria such as Stopping menstruation for 12 months or more and at least two times flashing in day. they are excluded If missing the drug more than two days and development of drug complication. Sample size is estimated 45 in each group according to previous studies and statistical formula. Sampling method is conveniences, but samples are randomly assigned to three groups of receiving black cohosh, Agnugol and control using stratification method base on Questionnaire scores . Women in intervention groups are asked to consume one coated pills of black or Agnugol every night before going to bed for 8 weeks. Study instruments include a questionnaire for demographic variables and MRS questionnaire. Data were collected before starting intervention and the end of first and second months after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016030826971N1**
Registration date: **2016-06-11, 1395/03/22**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-06-11, 1395/03/22

Registrant information

Name

Marzeyeh Loripoor

Name of organization / entity

Rafsanjan University Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 34 3428 4950

Email address

m.loripoor@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Rafsanjan University
Medical Sceince

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative investigate the effect of black cohosh (simifugol) and vitexagnus _castus(agnugol) on menopausal symptoms

Public title

compare the effect of balack kohosh and vitexagnus on menopausal symptoms

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion measures: Getting 5 score from MRS questionnaire; Stopping menstruation for 12 months or

more than; Age between 45 to 65 years old; No history of breast and uterus cancers and abnormal vaginal bleeding, No history of depression and liver, kidney or thyroid diseases; Inform consent for participate in the study. Exclusion measures: Emerging side effects of drugs during the study; Forgetting to consume drugs more than two consecutive days in a week; Consuming other drugs such as progestin, anti-fertility pills and GNRH agonists and antagonists; Death of loved persons; Participate in new exercise program.

Age

From **45 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **135**

Randomization (investigator's opinion)

Randomized

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

using block randomization

Secondary Ids

empty

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

Ethics committee of Rafsanjan University Medical Science

Street address

Imam Ali street- cenral department of Rafsanjan University Medical Science

City

Rafsanjan

Postal code**Approval date**

2016-02-20, 1394/12/01

Ethics committee reference number

IR.IR.RUMS.REC.1394.183

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

menopausal symptoms

ICD-10 code

N95.1

ICD-10 code description

Symptoms such as flushing, sleeplessness, headache, lack of concentration, associated with menopause

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

menopausal symptoms

Timepoint

before intervention- end of first month- end of second month

Method of measurement

MRS questionnaire

Secondary outcomes**1****Description**

Possible Complications

Timepoint

Along with complications

Method of measurement

Inform the patient

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

intervantion group1:one Wired coated Simifugol tablet daily containing 6.5 mg of dried root Vogel Manufacturing Goldaru plant black kohesh drug for 8 weeks every night in the hour before bedtime preferably with some water intervantion group2: one Enteric-coated Agnogol tablet daily containing 4.8 mg dried fruit extract herb Vitex (vitex-agnus castus) Manufacturing Goldaru plant, in a period of 8 weeks, every night before bed

Category

Treatment - Drugs

2**Description**

control group: No drugs and just will fill the questionnaire at certain times

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Health therputic center 7

Full name of responsible person

Fatemeh Fatholahi

Street address

Bvd Imam Reza

City

Rafsanjan

2**Recruitment center****Name of recruitment center**

Health therputic center3

Full name of responsible person

Esmat Heidari

Street address

Shareati street

City

Rafsanjan

3**Recruitment center****Name of recruitment center**

Health therputic center 4

Full name of responsible person

Shaabani Farzaneh

Street address

Amirkabir Street

City

Rafsanjan

4**Recruitment center****Name of recruitment center**

Health therputic centerr 1

Full name of responsible person

Zohreh Samareh

Street address

Imam street

City

Rafsanjan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**Vice chancellor for research Rafsanjan University
Medical Science**Full name of responsible person**

Dr Hamid Hakimi

Street addressImam Ali street- The head office of the University of
Medical Sciences-Research and Education Deputy**City**

Rafsanjan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding sourceVice chancellor for research Rafsanjan University Medical
Science**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**

Rafsanjan University Medical Science

Full name of responsible person

marzeyeh loripoor

Position

phd of reproductive health- assistant professor

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

faculty of Rafsanjan Nursing and Midwifery

City

Rafsanjan

Postal code**Phone**

+98 34 3425 5900

Fax

+98 34 3425 8497

Email

m.loripoor@rums.ac.ir

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

Rafsanjan University Medical Science

Full name of responsible person

marzeyeh loripoor

Position

phd

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

faculty of Rafsanjan Nursing and Midwifery

City

Rafsanjan

Postal code

7718796755

Phone

+98 34 3425 5900

Fax

+98 34 3425 8497

Email

m.loripoor@rums.ac.ir

Web page address

Person responsible for updating data

Contact

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