

# 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

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

Health therputic center3

**Full name of responsible person**

Esmat Heidari

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Shareati street

**City**

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

Health therputic center 4

**Full name of responsible person**

Shaabani Farzaneh

**Street address**

Amirkabir Street

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

Health therputic centerr 1

**Full name of responsible person**

Zohreh Samareh

**Street address**

Imam street

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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 address**Imam 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 source**Vice 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

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**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*