

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

Comparative investigate the effect of vitexagnus _castus(agnugol) and Placebo on menopausal symptoms: a double-blind randomized clinical trial

Protocol summary

Summary

Objectives:The aim of this study is Comparative investigate the effect of vitexagnus _castus(agnugol) and Placebo on menopausal symptoms. **Design:**This study is a randomized clinical trial,double-blind ,placebo- control . **Setting and conduct:** the intervention period is 8-weeks.The demographic and Green questionnaires as well as .The samples are randomly divided into two separate groups. **Similarly. Participants :**The samples are 50 menopausal women aged 45 to 60 . The inclusion criteria consist of: age between 65-45 years; at least one year and a maximum of three years of their last menstrual period has passed; the number of hot flashes at least 2 times a day. **Exclusion criteria** consist of : smoking; at least for a period of 3 months are treated with hormones and antibiotics; systemic diseases such as kidney disease; blood pressure blood sugar; blood fat; depressed and anxious (anxiety and depression diagnosis based on diagnostic criteria DSM5 by psychiatrist); taking antithyroid drugs; gabapentin; SSRI; sulfonamides, methotrexate, Tryamtryn, sulfasalazine; the use of traditional medicines such as drug-induced flushing. **Intervention:** One group will receive capsules of vitexagnus _castus twice a day,next group of twice a day for 8 weeks . After 2 and 4 and 8 weeks participants will complete the questionnaires again . **main outcome :**The outcome of the The outcome of the study is improvement in menopausal symptoms.

General information

Acronym

Governmental

IRCT registration information

IRCT registration number: **IRCT2016120528967N3**

Registration date: **2016-12-31, 1395/10/11**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-12-31, 1395/10/11

Registrant information

Name

Safora Salemi

Name of organization / entity

Shahid Chamran University of Ahvaz

Country

Iran (Islamic Republic of)

Phone

+98 83 3821 1001

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e.mahmoudi@cobeldarou.com

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Expected recruitment start date

2017-01-08, 1395/10/19

Expected recruitment end date

2017-09-04, 1396/06/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative investigate the effect of vitexagnus _castus(agnugol) and Placebo on menopausal symptoms: a double-blind randomized clinical trial

Public title

Comparing effects of vitex agnus _castus (agnugol) and Placebo on menopausal symptoms

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 45-65 years; at least one year and a maximum of three years of their last menstrual period has passed; the number of hot flashes at least 2 times a day. Exclusion criteria: smoking; at least for a period of 3 months are treated with hormones and antibiotics; systemic diseases such as kidney disease; blood pressure blood sugar; blood fat; depressed and anxious (anxiety and depression diagnosis based on diagnostic criteria DSM5 by psychiatrist); taking antithyroid drugs; gabapentin; SSRI; sulfonamides, methotrexate, Tryamtryn, sulfasalazine; the use of traditional medicines such as drug-induced flushing.

Age

From 45 years old to 65 years old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 50

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

Ethics committee of Kermanshah University of Medical Sciences

Street address

Building No.2, Shahid Beheshti Blvd, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Postal code

Approval date

2016-10-19, 1395/07/28

Ethics committee reference number

kums.rec.1395.442

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- 2 weeks later- 4 weeks later- 8 weeks later

Method of measurement

Green Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

First group will be given Tab agnugol oral, 2 times daily for 8 weeks.

Category

Treatment - Drugs

2

Description

Second group will be Placebo Tab oral, 2 times daily for 8 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Red Crescent Clinics

Full name of responsible person

Ali Rahmani

Street address

Red Crescent clinics, Shahid Beheshti Blvd

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kermanshah University of Medical Sciences

Full name of responsible person

Koroush Hamzehee

Street address

Building No.2, Shahid Beheshti Blvd, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

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, Kermanshah 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Vahid Farnia

Position

Psychiatrist

Other areas of specialty/work

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Farabi Hospital, Isar square

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Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical

Full name of responsible person

Safora Salemi

Position

Psychologist

Other areas of specialty/work

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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