Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Combined Effect of black cohosh, soybean, arctium lappa L and vitex agnus- castus extracts on clinical symptoms, biomarkers of oxidative stress biomarkers and inflammation among menopausal women

Protocol summary

Study aim
Determining the combined effect of black cohosh, soybean, arctium lappa L and vitex agnus- castus extracts on clinical symptoms, biomarkers of oxidative stress biomarkers and inflammation among menopausal women

Design
Random assignment was done by the use of computer-generated random numbers. Population and sample size: In the study 54 patients who having menopause symptom among patients of eligible and referred to Kousar hospital affiliated to Qazvin University of Medical Sciences, Qazvin, Iran, will be selected.

Settings and conduct
The present study will be performed in Kousar hospital affiliated to Qazvin University of Medical Sciences, Qazvin, Iran. Patients are randomly divided into two groups receiving supplements and placebo. All people taking the supplement or placebo will take the medicine for eight weeks. Before and after the intervention, venous blood samples will be taken from the patient after 12 hours of fasting for relevant tests.

Participants/Inclusion and exclusion criteria
Inclusion criteria: fatty liver, no gastrointestinal diseases, no smoking and alcohol Exclusion criteria: thyroid disease, breast and ovary cancer , diabetes, Liver disorders, nerves, blood pressure, taking anticoagulants

Intervention groups
Patients will be assigned to receive either combined extract (intervention group: n=27) or placebo (control group: n=27).

Main outcome variables
Clinical signs including symptoms and complications of menopause respect to vasomotor, psychosocial, and physical activity, and also biomarkers of oxidative stress and inflammation in patients with menopausal symptoms will be measured before and after the intervention.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170430033730N8**
Registration date: **2021-03-11, 1399/12/21**
Registration timing: **registered_while_recruiting**

Last update: **2021-03-11, 1399/12/21**
Update count: **0**

Registration date
2021-03-11, 1399/12/21

Registrant information

Name
Seyyed Mehdi Mirhashemi

Name of organization / entity
Qazvin University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-02-13, 1399/11/25

Expected recruitment end date
2021-03-15, 1399/12/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The Combined Effect of black cohosh, soybean, arctium lappa L and vitex agnus- castus extracts on clinical symptoms, biomarkers of oxidative stress biomarkers and inflammation among menopausal women

Public title
The Combined Effect of black cohosh, soybean, arctium lappa L and vitex agnus- castus extracts On menopause

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Having menopausal symptoms

Exclusion criteria:
patients who do not want to cooperate People who smoke People who drink alcohol Patients with gastrointestinal disorders Diabetic Patients Thyroid disease, breast and ovarian cancer, liver and neurological disorders, high blood pressure, taking anticoagulants

Age
From **45 years** old to **55 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **54**

Randomization (investigator's opinion)
Randomized

Randomization description
54 eligible patients are assigned to groups A and B equally using the balanced block randomization method and the online system sealedenvelope.com. The relevant list is generated using blocks with variable sizes of 6 and 8. The created list consists of eight blocks, of which five blocks are 6 and three blocks are 8. The order of the blocks and the people in each block is completely random and each person is assigned a unique code.54 similar envelopes are selected. A unique code is registered on each package based on the mentioned list. Depending on the study groups, supplement (A) or placebo (B) is included. The envelopes are closed and each envelope is assigned to one participant.

Blinding (investigator's opinion)
Double blinded

Blinding description
Placebo is used for blinding. Supplements and placebo are poured into containers that are similar in size, shape and appearance. Instead of group names, each container is assigned a unique code. The researchers and the patient are blind until the final analysis.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Qazvin University of Medical Sciences

Street address
Shahid Bahonar Boulevard

City
Qazvin

Province
Qazvin

Postal code
34197-59811

Approval date
2020-02-29, 1398/12/10

Ethics committee reference number
IR.QUMS.REC.1398.372

Health conditions studied

1

Description of health condition studied
menopause

ICD-10 code
N95

ICD-10 code description
Menopausal and other perimenopausal disorders

Primary outcomes

1

Description
Clinical symptoms

Timepoint
Beginning and end of the study

Method of measurement
Quality of life questionnaire for menopausal women

Secondary outcomes

1

Description
Glutathione

Timepoint
Beginning and end of the study

Method of measurement

Spectrophotometry

2

Description
MDA
Timepoint
Beginning and end of the study
Method of measurement
Spectrophotometry

3

Description
TNF-α
Timepoint
Beginning and end of the study
Method of measurement
ELISA

4

Description
IL-8
Timepoint
Beginning and end of the study
Method of measurement
ELISA

5

Description
Gonadotropins
Timepoint
Beginning and end of the study
Method of measurement
ELISA

6

Description
E2
Timepoint
Beginning and end of the study
Method of measurement
ELISA

Intervention groups

1

Description
Intervention group: will receive two capsules of 550 mg of combined extract(Black cohosh, Soybean, Sweet potato, Greater burdock, Vitex) twice daily for 8 weeks. The capsules are manufactured by Barij Essence Pharmaceutical Company, Kashan, Iran.
Category
Treatment - Drugs

2

Description
Control group: Will take two capsules of 550 mg of placebo twice daily for 8 weeks. The Placebo are manufactured by Barij Essence Pharmaceutical Company, Kashan, Iran.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Kousar Hospital
Full name of responsible person
Seyyed Mehdi Mirhashemi
Street address
Shahid Taleghani Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Mohammad-Mehdi Emamjomeh
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research@qums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qazvin University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Seyyed Mehdi Mirhashemi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

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Professor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable