Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation the effect of a preparation from of Silybum marianum on hot flashes in postmenopausal women

Protocol summary

Study aim
Effect of Silybum marianum on hot flashes
Design
Double-blind clinical trial in postmenopausal women aged 40 to 60 with hot flushes. Patients are randomly selected on the basis of quadruple blocks for the use of one form of drug. Total volume: 80 in intervention and control groups
Settings and conduct
Participants are selected from 40 to 60 years old postmenopausal women with hot flashes referred to the Iranian Healthcare Center of Babol University of Medical Sciences. After completing the demographic data and personal consent, the GREEN and HFRDIS questionnaires were completed to determine the severity of the symptoms of the patients at the start, the 4th and 8th weeks during the treatment, and the 4th week after the completion of the treatment, and a questionnaire on the frequency of symptoms at the time of treatment was provided to patients delivered at the end of 8 weeks of treatment
Participants/Inclusion and exclusion criteria
Inclusion criteria 1: Patients aged 40 to 60 years. 2: Those who have had 3 times daily intake from the previous month. 3: People at least 12 and up to 60 months past the last month. 4: FSH> 40 Exit criteria: 1: People with underlying illness (liver, kidney, coagulation and metabolic disorders, such as thyroid problems). 2: People with a history of allergy to herbal medicines. 3: People who have a history of using anti-anxiety drugs,estrogen and progesterone hormones in the last 6 months, and other medicines that may affect hot flashes. 4: People with a history of asthma and allergies. 5. Pap smear and uterine ultrasonography are reported to be pathologic. 6. Mass or malignancy in the breast, ovary
Intervention groups
Patients were randomly divided into two groups the control group (Placebo capsule, 250 mg, twice daily) and the treatment group ("Silybum marianum" capsule, 250 mg, twice daily).
Main outcome variables
Severity and frequency of hot flashes

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190223042811N1**
Registration date: **2019-06-03, 1398/03/13**
Registration timing: **registered_while_recruiting**

Last update: **2019-06-03, 1398/03/13**
Update count: **0**
Registration date
2019-06-03, 1398/03/13

Registrant information
Name
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-01-05, 1397/10/15
Expected recruitment end date
2020-01-05, 1398/10/15
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of a preparation from of Silybum marianum on hot flashes in postmenopausal women

Public title

Effect of Silybum marianum extract on hot flash symptoms in postmenopausal women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged 40 to 60 years old. 3 times daily from a previous month. Individuals who have been treated at least People who are at least 12 and at most 60 months have passed since the last month. (Menopause) FSH>40

Exclusion criteria:

Use smoking, Valkel cigarettes. People with underlying diseases (liver, kidney, metabolic disorders such as thyroid problems) are. They have a history of sensitivity to herbal medicines. People who have a history of using anxiolytics, antidepressant, estrogen and progesterone hormones in the last 6 months, use anticoagulant and anti-inflammatory drugs like ibuprofen and other drugs affecting hot flashes. People who have a history of asthma and allergies. Pathologic and ultrasonography have been reported in the uterus. Have a history of mass or malignancy in the breast, ovary or uterus. Do not have natural blood pressure. Have a history of thromboembolism.

Age

From **40 years** old to **60 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of randomization in this study is quadruple blocking method and the randomization unit is individual and tool is statistical software. The sequencing will be done by quadruple blocking. Concealing done by using similar capsule box form for both groups, and the data analyzer knows how to allocate the intervention.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients and the intervening person are completely unaware of which drug they received and delivered.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Institutional Research Ethics Committee, Health Research Institute, Babol University of Medical Scie

Street address

University of Medical Sciences, Babol University of Medical Sciences, Babol, Iran

City

Babol

Province

Mazandaran

Postal code

4615973899

Approval date

2019-01-05, 1397/10/15

Ethics committee reference number

IR.MUBABOL.HRI.REC.1397.231

Health conditions studied

1

Description of health condition studied

Hot flashes

ICD-10 code

N95.1

ICD-10 code description

Menopausal and female climacteric states

Primary outcomes

1

Description

Hot flashes

Timepoint

At the beginning of treatment, weeks 4 and 8 during treatment and 4 weeks after treatment

Method of measurement

The standard GREEN questionnaire, HFRDIS

2

Description

The frequency of hot flashes

Timepoint

At the beginning of treatment, weeks 4 and 8 during treatment and 4 weeks after treatment

Method of measurement

Daily Inventory of Hot flashes

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: capsules containing 250 mg of fruit extract "silybum marianum" twice a day for 8 weeks
Category
Treatment - Drugs

2

Description
Control group: capsules containing 250 mg of starch powder twice a day for 8 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Persian Medicine clinic, Babol university of medical sciences
Full name of responsible person
Zohreh Saberi
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available