

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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

zohreh saberi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

z.saberi@mubabul.ac.ir

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

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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Babol, Ganjafrouz Street , Persian Medicine clinic

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Babol University of Medical Sciences

Full name of responsible person

Zohreh Saberi

Position

Ph.D. student of Traditional Medicine

Latest degree

Medical doctor

Other areas of specialty/work

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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