Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of borage tea on sleep disorders in postmenopausal women

Protocol summary

Study aim
Determining the effect of borage tea on sleep disorders in postmenopausal women
Design
A two-group clinical trial with parallel groups is performed on 60 people. In both groups, the intervention is performed with borage tea or Wheat germ tea. Study is two-blinded. Sampling done with simple method and random allocation was done.
Settings and conduct
The ethical aspects were investigated and confirmed by the Research Ethics Committee of AJUMS, and the necessary permissions were obtained. Participants who had the inclusion criteria enrolled in this one-blinded study and randomization was conducted in A or B groups.
Participants/Inclusion and exclusion criteria
Inclusion criteria: amenorrhea for at least 12 months. 45-60 years old. Score more than 5 on the Pittsburgh Questionnaire Exclusion criteria: Occurrence of any physical or psychological disorder during the study that causes sleep disorders. Discontinuation of borage tea consumption by the subject for any reason before the end of the intervention period. Having an underlying disease (hypertension - diabetes). Use of hormone therapy. Having chronic disease (heart, renal, diabetes, hypertension). Consumption of alcohol and addictive substances. Having an allergy to borage tea. Taking benzodiazepines pills during the last 3 months.
Intervention groups
This study have 2 groups. Group A: receives borage tea. Group B: receives Wheat germ tea.
Main outcome variables
Sleep disorders in postmenopausal women.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200925048838N1**
Registration date: **2020-10-12, 1399/07/21**
Registration timing: **prospective**

Last update: **2020-10-12, 1399/07/21**
Update count: **0**
Registration date
2020-10-12, 1399/07/21

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-11-10, 1399/08/20
Expected recruitment end date
2021-02-08, 1399/11/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of borage tea on sleep disorders in postmenopausal women

Public title
The effect of borage tea on sleep disorders in postmenopausal women
Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Amenorrhea for at least 12 years. 60-45 years old. Score more than 5 on the Pittsburgh Questionnaire

Exclusion criteria:

Occurrence of any physical or psychological disorder during the study that causes sleep disorders. Discontinuation of borage tea consumption by the subject for any reason before the end of the intervention period Having an underlying disease (hypertension - diabetes) Use of hormone therapy. Having Chronic disease (heart, kidney, diabetes, hypertension) Consumption of alcohol and addictive substances. Having an allergy to borage Taking benzodiazepines pills during the last 3 months.

Age

From **45 years** old to **60 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is performed using a random number table to create quadruple blocks in a one-to-one ratio that will be placed in two groups of 30 people to intervene and control.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, according to the apparent simulation in prescription tea and the use of a cup of the same size for similarity of the concentration of the substance in the two groups, the researcher and the participants do not know each person is in which group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz University of Medical Sciences

Street address

Esfand Ave., Golestan Blvd., Ahvaz

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Khouzestan

Postal code

15794 - 61357

Approval date

2019-12-09, 1398/09/18

Ethics committee reference number

IR.AJUMS.REC.1399.156

Health conditions studied

1

Description of health condition studied

sleep disorders in postmenopausal women.

ICD-10 code

G47

ICD-10 code description

Sleep disorders

Primary outcomes

1

Description

Sleep disorder in postmenopausal women.

Timepoint

Pre-intervention, 8 weeks after the start of the intervention

Method of measurement

Variables are measured by demographic questionnaire, Pittsburg Sleep Quality Index (PSQL) and Insomnia Severity Index (ISI).

Secondary outcomes

1

Description

Sleep disorders in postmenopausal women.

Timepoint

Pre-intervention, 8 weeks after the start of the intervention.

Method of measurement

Variables are measured by demographic questionnaire, Pittsburg Sleep Quality Index (PSQL) and Insomnia Severity Index (ISI).

Intervention groups

1

Description

Intervention group: For this patient, if they have the inclusion criteria, after providing explanations about the dissertation plan and obtaining informed consent; before the intervention, the demographic information form,

PSQL questionnaire and ISI questionnaire will be completed. 2-grams of borage tea is applied every night before going to bed for 8 weeks. a cup of the same size is purchased and given to all intervention groups to determine the same concentration. 8 weeks after the intervention, the questionnaires will be completed again by all subjects.

Category

Treatment - Other

2

Description

Control group: For this patient, if they have the inclusion criteria, after providing explanations about the dissertation plan and obtaining informed consent; before the intervention, the demographic information form, PSQL questionnaire and ISI questionnaire will be completed. In the control group, the intervention is applied by placebo. The placebo will also contain wheat germ powder in a 2-grams bag, which is quite similar in appearance to the bag containing 2-grams of borage tea and is given every night before bed for 8 weeks. Also, for all members of the group, a cup of the same size is purchased and given to determine the uniform concentration of the placebo. 8 weeks after the intervention, the questionnaires will be completed again by all subjects. It should be noted that the ineffectiveness of wheat germ on sleep disorders has been proven.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Tabatabai Hospital Clinic, Baghmalek

Full name of responsible person

Leila Ghasemzadeh Dehkordi

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Leila Ghasemzadehdehkorde

Position

Master student of Midwifery

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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