Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of lavandula and citrus aurantium on depression and sleep quality in menopausal women

Protocol summary

Summary

The aim of this study is to compare the effect of lavandula and citrus aurantium on depression and sleep quality in menopausal women.This study is a randomized clinical trial, triple- blind, controle with placebo. The samples are postmenopausal women aged 45 to 60.The sample size is 156 women and the intervention period is 8-weeks. These women randomly were allocated into 3 groups (citrus aurantium, lavender and placebo) based on3 and 6 blocks randomization method. The same capsules Contains of 500 mg citrus aurantiumand lavender flower's Powder and placebo(starch) prepared by Yashil drug Sahand Pharmacotical Company. For allocation concealment, drugs and placebo were placed in the same closed opaque envelopes that serial numbered according to allocation sequence. Block scheduling and preparing envelopes were performed by a person not involved in the sampling and data analysis. They will enter to study by the order number on the envelope. For reminding, 2 and 6 weeks after the start of the study phone call with participants will be taken by the researcher.Sleep quality and depression in all three groups before and after intervention will be measured by Pittsburgh and Beck questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201504236582N11**
Registration date: **2015-10-09, 1394/07/17**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-10-09, 1394/07/17

Registrant information

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2016-04-18, 1395/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of lavandula and citrus aurantium on depression and sleep quality in menopausal women

Public title

Comparison of the effect of lavandula and citrus aurantium on depression and sleep quality in menopausal women

Purpose

Supportive

Inclusion/Exclusion criteria

The inclusion criteria: 45-60 years old; 1 to 6 years after

the last menstrual period which start by natural menopause; getting more than 5 score from Pittsburgh Sleep Quality Index (PSQI);getting between4-28 score from Beck depression score; not taking hypnotic and anti depressant drugs; not taking tobacco and alcohol; having phone number for follow-up; without history of asthma and allergy to specific plants or citrus; Lack of acute gastrointestinal problems declared by herself; Living in Urmia; the desire to participate in the study Exclusion Criteria: Having travel or home change during intervention; Having a history of severe physical and mental disease that causes sleep disorders and depression; Death of a relative in the past three months, encounter with the events that caused sleep disorders and depression; Regular weekly or professional exercise; The use of other methods of traditional medicine

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

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **156**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple 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 Tabriz University of Medical Sciences

Street address
Tabriz University of Medical Sciences Research Administration

City
Tabriz

Postal code

Approval date
2015-05-11, 1394/02/21

Ethics committee reference number
TBZMED.REC.1394.98

Health conditions studied

1

Description of health condition studied
sleep quality

ICD-10 code
N95.1

ICD-10 code description
Menopausal and female climacteric states

2

Description of health condition studied
depression

ICD-10 code
F32.0

ICD-10 code description
Depressive episode

Primary outcomes

1

Description
sleep quality

Timepoint
before and 8 week after intervention

Method of measurement
Pittsburgh Sleep Quality Index

2

Description
depression

Timepoint
before and 8 week after intervention

Method of measurement
Beck Depression Questionnaire

Secondary outcomes

1

Description
Satisfaction of postmenopausal women

Timepoint
8 weeks after intervention

Method of measurement
Checklist

2

Description
Anxiety

Timepoint
Before and 8 weeks after intervention

Method of measurement
(STAI) questionnaire

3

Description
Adverse events
Timepoint
8 weeks after intervention
Method of measurement
Checklist

4

Description
Personal and social characteristics associated with depression and sleep quality scores in the groups studied
Timepoint
Before intervention
Method of measurement
Demographic questionnaire

Intervention groups

1

Description
The citrus aurantium group will receive capsules containing 500 mg Citrus aurantium flower's Powder twice a day after breakfast and dinner for 8 weeks.
Category
Treatment - Drugs

2

Description
The lavender group will receive capsules containing 500 mg of Lavender flower's Powdertwice a day after breakfast and dinner for 8 weeks.
Category
Treatment - Drugs

3

Description
The control group will receive capsules containing 500 mg starchtwice a day after breakfast and dinner for 8 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza Hospital
Full name of responsible person
Mahsa Namadian
Street address
City
Urmia

2

Recruitment center
Name of recruitment center
Fatemie Hospital
Full name of responsible person
Mahsa Namadian
Street address
City
Urmia

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mahin Kamalifard
Street address
Nursing and Midwifery, Tabriz University of Medical Sciences
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Name of organization / entity
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Person responsible for scientific inquiries

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Person responsible for updating data

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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