

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of oral capsule and aroma of lavender on the quality of sleep in perimenopausal women

Protocol summary

Study aim

Comparison of the effect of oral capsule and aroma of lavender on the quality of sleep in perimenopausal women

Design

Clinical trials with control group, with parallel groups, Randomized, placebo-controlled, single-center. Sample size was 30 patients (2 groups of 15 control and intervention).

Settings and conduct

The study site is the Tuba Clinic in Sari city. Lavender essential oil with 100% concentration was used for the intervention group and 250 mg placebo capsule for the control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women aged 39-51 in transient menopausal period; Healthy sense of smell; No taking sleeping pills during the last month. Exclusion criteria: Drug addiction; History of mental disorders; History of asthma, bronchitis, chronic respiratory diseases.

Intervention groups

Intervention group: Lavender essential oil with 100% concentration (Barij Herbal Medicines Company of Kashan) is placed on a 2x2 piece of gas when going to bed at night and attaches to the patient's collar. Control group: 250 mg placebo capsule (brand name Linazepam) given to patients when going to bed at night.

Main outcome variables

Sleep Quality.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151228025732N47**

Registration date: **2019-12-18, 1398/09/27**

Registration timing: **registered_while_recruiting**

Last update: **2019-12-18, 1398/09/27**

Update count: **0**

Registration date

2019-12-18, 1398/09/27

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-19, 1398/08/28

Expected recruitment end date

2020-05-17, 1399/02/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of oral capsule and aroma of lavender on the quality of sleep in perimenopausal women

Public title

Comparison of the effect of oral capsule and aroma of lavender on the quality of sleep in perimenopausal women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
 Women aged 39-51 in transient menopausal period
 Healthy sense of smell No taking sleeping pills during the last month

Exclusion criteria:
 Drug addiction History of mental disorders History of asthma, bronchitis, chronic respiratory diseases

Age
 From **39 years** old to **51 years** old

Gender
 Female

Phase
 0

Groups that have been masked
No information

Sample size
 Target sample size: **30**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Patients are allocated randomly with simple sequential allocation in one of the two study groups by help of sealed envelope and receive the intervention of the same group. The unit of randomization is patient. Sealed envelopes are delivered to expert. With each patient's visit, one of the envelopes is randomly selected by the patients and determines the study group. The stratification approach is not used.

Blinding (investigator's opinion)
 Not 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 Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences, Basij Blvd, Semnan

City

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Province

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Postal code

3514799442

Approval date

2019-11-19, 1398/08/28

Ethics committee reference number

IR.SEMUMS.REC.1398.201

Health conditions studied

1

Description of health condition studied

Sleep

ICD-10 code

F51.12

ICD-10 code description

Insufficient sleep syndrome

Primary outcomes

1

Description

Sleep Quality

Timepoint

Before intervention and after intervention (one month later)

Method of measurement

PSQI- Pittsburgh Sleep Quality Index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Lavender essential oil with 100% concentration (Barij Herbal Medicines Company of Kashan) is placed on a 2x2 piece of gas when going to bed at night and attaches to the patient's collar.

Category

Treatment - Other

2

Description

Control group: 250 mg placebo capsule (brand name Linazepam) given to patients when going to bed at night.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Tuba Clinic

Full name of responsible person

Mohammadreza Asgari

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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
Semnan 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

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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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available