Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparing the effect of violet almond oil with almond oil and placebo in quality of sleep in patients with chronic insomnia

Protocol summary

Summary

Primary insomnia patients were detected by a neurologist based on the diagnostic criteria in DSM-V. The included patients were those whose illness had lasted at least three months and were willing to participate in a research project. The patients were referred to the Clinic of Traditional and Complementary Medicine in Mashhad University of Medical Sciences. After obtaining informed consent, they were randomly divided into three groups: A, B, C. The three groups received three drops of almond oil or violet-almond oil or placebo on each nostril every night. Since the treatment of chronic insomnia cares about sleep hygiene, due to moral considerations and lack of deprivation of treatment in the placebo group, sleep hygiene instructions were presented to all the three groups based on the guidelines of the American Association sleep (AASM). Before and after 30 days of treatment, Pittsburgh Sleep Quality Index, Insomnia Severity, was completed by all patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015120125335N1**
Registration date: **2016-02-19, 1394/11/30**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-02-19, 1394/11/30

Registrant information

Name

Zohre Feyzabadi

Name of organization / entity

Faculty of Traditional and Complementary Medicine, Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3855 2188

Email address

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2016-01-21, 1394/11/01

Expected recruitment end date

2016-05-21, 1395/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of violet almond oil with almond oil and placebo in quality of sleep in patients with chronic insomnia

Public title

Comparing the effect of violet almond oil with almond oil and placebo in chronic insomnia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Willingness to cooperate; Having the pre-defined conditions of insomnia according to DSM-V-TR; Suffering from insomnia for at least 3 months; Being between 18 and 60 years old; Lack of physical diseases such as lung diseases, allergic rhinitis, cardiovascular, infectious diseases, cancer; Lack of mental illnesses such

as depression, substance and drug abuse; Lack of neurological diseases such as Parkinson's and Alzheimer's disease; lack of sleep disorders like sleep apnea; lack of using drug and non-drug treatments for insomnia. Exclusion criteria: Pregnant and lactating women; History of allergy to medicinal herbs; Side effects of drugs; Irregular use of medication or treatment discontinuation; unwillingness to continue cooperation for any reason.

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **75**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Mashhad University of Medical Sciences

Street address
Building Qureshi, Daneshgah Ave.

City
Mashhad

Postal code

Approval date
2015-12-09, 1394/09/18

Ethics committee reference number
IR.mums.fm.REC.1394.461

Health conditions studied

1

Description of health condition studied
chronic insomnia

ICD-10 code
F51.0

ICD-10 code description
Nonorganic insomnia

Primary outcomes

1

Description
sleep

Timepoint
Before the intervention and one month after intervention

Method of measurement
Pittsburgh questionnaire, Insomnia Severity Index questionnaire

Secondary outcomes

1

Description
Side effects

Timepoint
The end of study

Method of measurement
Questionnaire

Intervention groups

1

Description
In the first group of intervention, patients receive 3 drops of almond violet oil in each nostril every night before sleep for a duration of one month. Each drop contains 33 mg of the drug.

Category
Treatment - Drugs

2

Description
In the placebo group, patients receive 3 drops of placebo in each nostril every night before sleep for a duration of one month.Each drop contains 33 mg of the placebo.

Category
Placebo

3

Description
In the second group of intervention, patients receive 3 drops of sweet almond oil in each nostril every night before sleep for a duration of one month. Each drop contains 33 mg of the drug.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Traditional Medicine Clinic
Full name of responsible person
Zohre Feyzabadi
Street address
Faculty of Traditional and Complementary Medicine, East Razi Ave.
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Building Qureshi, Daneshgah Ave.
City
Mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Faculty of Traditional and Complementary Medicine, Mashhad University of Medical Sciences
Full name of responsible person
Zohre Feyzabadi
Position
assistant professor of Iranian traditional medicine
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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Web page address

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