Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the efficacy of the traditional medicine product of cucurbita pepo oil and placebo topically administered in patients with insomnia

Protocol summary

Study aim

To compare the efficacies of cucurbita pepo oil and placebo topically administered in patients with insomnia

Design

This phase II clinical trial will be performed in a randomized manner. A total of 74 primary chronic insomnia patients referring to Baharlou Sleep Disorders Clinic of Tehran will be randomly allocated into intervention and control groups via simple random allocation method.

Settings and conduct

This is a double-blinded study where the participants and caregivers are not aware of the drugs used in the groups. A total of 74 insomnia patients referred to the Tehran-based Sleep Disorders Bahralou Clinic will be recruited in a non-randomized manner according to inclusion criteria. They will be assigned randomly into intervention and placebo groups (n=37 per group) using the table of random numbers. Patients in the intervention and the placebo groups will receive, respectively, two drops of cucurbita pepo oil and liquid paraffin in the nose one hour before bedtime for two weeks.

Participants/Inclusion and exclusion criteria

Main inclusion criteria: age between 20 to 65 years; individuals with sleep difficulty despite observance of sleep health tips; and those who have trouble starting sleep. Main exclusion criteria: having associated physical diseases that cause insomnia; history of drug abuse; and pregnant and breastfeeding women.

Intervention groups

Intervention group (cucurbita pepo oil): Members of the intervention group will receive two drops of cucurbita pepo oil in the nose one hour before bedtime for two weeks. Placebo group (liquid paraffin): Members of the control group will receive two drops of liquid paraffin in the nose one hour before bedtime for two weeks.

Main outcome variables

Sleep quality, subjective quality of sleep, sleep efficiency, delayed sleep initiation, and insomnia severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180424039397N1**
Registration date: **2018-09-19, 1397/06/28**
Registration timing: **registered_while_recruiting**

Last update: **2018-09-19, 1397/06/28**
Update count: **0**

Registration date

2018-09-19, 1397/06/28

Registrant information

Name

Elham Haghjoo

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5558 0388

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e_haghjoo_56@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the efficacy of the traditional medicine product of cucurbita pepo oil and placebo topically administered in patients with insomnia

Public title
The impact of cucurbita pepo oil on insomnia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 20 to 65 years Individuals with sleep difficulty despite observance of sleep health tips Those who have trouble starting sleep or those who are not satisfied with their sleep quality, or both. Patients who score 3 or greater for either of the first two items on the Insomnia Severity Index Patients whose total score of the first two items on the Insomnia Severity Index is 4 or greater, and whose main complaint is insomnia.
Exclusion criteria:
Having associated physical diseases such as cancer that cause insomnia Having mental diseases such as psychosis Having a history of drug abuse Having neurological diseases such as the Parkinson's disease, Alzheimer's disease, and epilepsy Pregnant and breast-feeding women History of allergy to medicinal herbs
Age
From **20 years** old to **65 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **74**
Randomization (investigator's opinion)
Randomized
Randomization description
The eligible individuals will be allocated to either the intervention or control group using the table of random numbers.
Blinding (investigator's opinion)
Double blinded
Blinding description
At first, the objectives of the study will be explained to the participants. the hospitalized patients will receive the drug or placebo by a nurse. however, neither the participants nor the nurses will be aware of the given medication.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Iran University of Medical Sciences
Street address
Hemmat Expressway
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2018-03-13, 1396/12/22
Ethics committee reference number
IR.IUMS.REC.1396.9321309013

Health conditions studied

1

Description of health condition studied
Primary insomnia
ICD-10 code
F51.01
ICD-10 code description
Primary insomnia

Primary outcomes

1

Description
Sleep quality
Timepoint
Before intervention, one week after the study onset, after intervention is finished
Method of measurement
Sleep log form

2

Description
Subjective Quality of Sleep
Timepoint
Before intervention, one week after the study onset, after the intervention is finished
Method of measurement
Sleep log form

3

Description
Sleep efficiency
Timepoint
Before intervention, one week after the study onset, after the intervention is finished
Method of measurement

Sleep log form

4

Description
Delayed sleep initiation
Timepoint
Before intervention, one week after the study onset, after the intervention is finished
Method of measurement
Sleep log form

5

Description
Insomnia severity
Timepoint
Before intervention, one week after the study onset, after the intervention is finished
Method of measurement
Insomnia Severity Index

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group (cucurbita pepo oil): Members of the intervention group will receive two drops of cucurbita pepo oil in the nose one hour before bedtime for two weeks.
Category
Treatment - Drugs

2

Description
Control group (liquid paraffin): Members of the control group will receive two drops of liquid paraffin in the nose one hour before bedtime for two weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Sleep Disorders Bahralou Clinic
Full name of responsible person
Dr Elham Haghjoo
Street address
Railway Square
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12299
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+98 21 3256 8707
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr Seyed Kazem Malekouti
Street address
Hemmat Highway
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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
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Dr Elham Haghjoo
Position
Assistant in Iranian Traditional Medicine
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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
Not applicable
Title and more details about the data/document
Deidentified Individual Participant Data Set The file will be provided in axcel file format.
When the data will become available and for how long
From the time the article extracted from the project is published for 6 months
To whom data/document is available
to researchers
Under which criteria data/document could be used
for research and scientific purposes
From where data/document is obtainable
Personal correspondence via email to the article authors
What processes are involved for a request to access data/document
email correspondence
Comments