

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 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 Baharlou 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

##### Email address

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

###### **City**

Tehran

###### **Province**

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###### **Postal code**

12299

###### **Phone**

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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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###### **Phone**

+98 21 6650 6128

###### **Email**

kmalakouti@iums.ac.ir

##### **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**

Medical doctor

###### **Other areas of specialty/work**

General Practitioner

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Hasanabad Square

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
Dr Asieh Shojaei  
**Position**  
Associate Professor in Pharmacognosy  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Birjand University of Medical Sciences  
**Full name of responsible person**  
Mohammad Bagher Roozgar  
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Translator  
**Latest degree**  
Master

### Other areas of specialty/work

Others  
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Ghaffari Ave.  
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**Email**  
roozgar@bums.ac.ir

## 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 excel 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