Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Hypnotic effect of Lactuca sativa seed in patients with insomnia: a randomized double-blind clinical trial

Protocol summary

Study aim

The purpose of this study is to evaluate the hypnotic effect of lettuce seeds (Lactuca sativa L.) in insomnia patients in a double-blind clinical trial.

Design

Clinical trial of phase 2-3 with control and intervention groups, with parallel groups, double blind, randomized

Settings and conduct

This clinical trial will be performed on 60 patients with primary sleep disorder. Patients are randomly divided into two groups of 30 each, that the patients are randomly assigned to a bottle containing placebo or herbal syrup. The unique codes make by the software are used on drug boxes. In addition to the first visit, patients will be visited at the end of the fourth week after receiving the medication. Sleep quality in both groups will be measured before and after the intervention using the standard Pittsburgh Sleep Quality Questionnaire. This questionnaire is designed to assess individuals' sleep quality and includes seven questions.These items are scored on a scale of 0 to 3 by the subjects studied, resulting in scores of 0 to 21. Higher scores are considered as worse sleep quality.

Participants/Inclusion and exclusion criteria

People aged 20 to 50 years who have a history of primary insomnia disorder (people with this disorder have difficulty starting and maintaining sleep and feel tired and restless after waking up) will be included in the study. Patients with a history of secondary insomnia disorder, such as insomnia due to medication use, or sleep disorder related to another mental disorder will not be included in the study.

Intervention groups

Patients were randomly divided into two groups of 30 each, with one group receiving lettuce syrup and the other receiving placebo for four weeks each night. Two groups will receive routine insomnia medications during the study.

Main outcome variables

subjective sleep quality; Sleep Time; Sleep Duration; daytime dysfunction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200128046288N1**
Registration date: **2020-04-15, 1399/01/27**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-15, 1399/01/27**
Update count: **0**

Registration date

2020-04-15, 1399/01/27

Registrant information

Name

Fereshteh Golfakhrabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3373 8378

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-18, 1398/12/28

Expected recruitment end date

2020-05-19, 1399/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Hypnotic effect of Lactuca sativa seed in patients with insomnia: a randomized double-blind clinical trial

Public title
Hypnotic effect of Lactuca sativa seed in patients with insomnia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
People 20 to 50 years History of Primary Insomnia Disorder (People with sleep disorders have difficulty starting and maintaining sleep and feel tired and restless after waking up. Their daily functioning decrease and they are constantly thinking of having a restful sleep. The women in the study had a negative pregnancy test and had appropriate prevention methods during the study. No history of asthma and heart disease (heart block and heart failure) Patients should not use analgesic drugs regularly for any reason

Exclusion criteria:
A history of secondary insomnia disorder, such as insomnia from medication use, or sleep disorder related to another mental disorder Pregnancy and Lactation History of heart, kidney or liver disease History of neurological and neurological diseases History of diabetes

Age
From **20 years** old to **50 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
For randomization, the permuted block randomization will be used with quadruple blocks. blocks will be produced by using the online site (www.sealedenvelope.com)

Blinding (investigator's opinion)
Double blinded

Blinding description
Unique codes, which is generated by the software, will be used on the drug and placebo boxes. By entering each individual into the study based on the produced sequence, the drug or placebo box in which the code is registered, will be assigned to the individual. During the research, the randomization list is held by the statistic consultant, and the participants, the project implementer and all those who participate in the measurement of the indicators will not be aware of the assigned groups

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences,

Street address
Ahvaz Jundishapur University of Medical Sciences,, Golestan street

City
Ahvaz

Province
Khouzestan

Postal code
-61357-15794

Approval date
2019-07-19, 1398/04/28

Ethics committee reference number
IR.AJUMS.REC.1398.424

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
subjective sleep quality

Timepoint
In addition to the first visit, patients will be visit at the end of the fourth week after receiving the medication

Method of measurement
Pittsburgh Sleep Quality Questionnaire

2

Description
Sleep Time

Timepoint
In addition to the first visit, patients will be visit at the end of the fourth week after receiving the medication

Method of measurement
Pittsburgh Sleep Quality Questionnaire

3

Description
Sleep Duration
Timepoint
In addition to the first visit, patients will be visit at the end of the fourth week after receiving the medication
Method of measurement
Pittsburgh Sleep Quality Questionnaire

4

Description
daytime dysfunction
Timepoint
In addition to the first visit, patients will be visit at the end of the fourth week after receiving the medication
Method of measurement
Pittsburgh Sleep Quality Questionnaire

Secondary outcomes

1

Description
The rate of drug side effects
Timepoint
During drug use
Method of measurement
Patient Report

Intervention groups

1

Description
Intervention group: They will receive 15 ml of lettuce seed syrup that will be made by the researchers of the present Project, every night for four weeks. Each 15 ml of syrup contains 100 mg total phenols as gallic acid equivalents. The intervention group will receive their routine insomnia medications during the study.
Category
Treatment - Drugs

2

Description
Control group: They will receive placebo syrup every night for four weeks.The control group will receive their routine insomnia medications during the study.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Medical office
Full name of responsible person
Alireza Hassanzadeh
Street address
kianpars street
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6155955634
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Badavi
Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan street
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6135733184
Phone
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Email
Badavim@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person
Fereshteh Golfakhrabadi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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Person responsible for scientific inquiries

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Position
Assistant professor

Latest degree
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Other areas of specialty/work
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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
Yes - There is 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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Only part of the data will be shared

When the data will become available and for how long
The access time is up to 6 months after the results are published

To whom data/document is available
Six months after the publication of articles from this study, the data obtained will be made available to the applicant researchers for further analysis.

Under which criteria data/document could be used
Six months after the publication of articles from this study, the data obtained will be made available to the applicant researchers for further analysis.

From where data/document is obtainable
Applicants can email the responsible author to receive the requested data

What processes are involved for a request to access data/document
Applicants will have access to the data from the present study by emailing the responsible author for up to one month.

Comments