Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigation of efficacy of "Monavvem" capsule comparing to placebo on the quality of sleep in patients with chronic insomnia

Protocol summary

Study aim

In this study, the therapeutic effects of Monavvem capsule versus placebo on chronic insomnia with high prevalence, physical complications and significant sociao-economical burden are studied.Thus, changes in mental quality of sleep, latency in sleep, sleep time, sleep efficiency, sleep disorders, need for sleep medication, patient daily function, ISI, PSQI, HAM-A, HAM- D is measured.

Design

Control group, groups, blind, randomized Clinical trials

Settings and conduct

Chronic insomnia patients are evaluated in sleep clinic based on DSM-5 and ICSD3 criteria and inform consent form. Subjects completed HAM-A, HAM-D, PSQI, and ISI questionnaires. Patients are randomly divided into two groups of placebo and placebo and randomly divided into two groups.In this study, 224 capsules or placebo were given to each group for eight weeks(4 capsules per day divided into 2 capsules each evening and 2 capsules each night before bedtime with a distance from the meal).The completed questionnaires will be completed in the fourth and eighth weeks.Patients are advised to complete the daily sleep information form at home.

Participants/Inclusion and exclusion criteria

Inclusion Criteria:Individuals aged 18 to 65 with the diagnosis of insomnia; ISI Score more than 7; no history of severe drug reaction to certain types of herbal medicines found in the drug; without using sleep aid medication in a week ago; Patients with the oral or written informed consent.Exclusion criteria: severe organic or psychiatric diseases as Parkinson's, Alzheimer's; alchohol or substance abuse; any other medication use or their withdrawal which affects sleep; history of blood coagulation disorders; other sleep disorders; pregnancy and lactation

Intervention groups

Drug group and placebo group

Main outcome variables

Severity index Insomnia, Total score of Pittsburgh, Hamilton's Anxiety Rating, Hamilton's Depression Scale Questionnaires

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190217042737N1**
Registration date: **2019-02-25, 1397/12/06**
Registration timing: **registered_while_recruiting**

Last update: **2019-02-25, 1397/12/06**
Update count: **0**

Registration date

2019-02-25, 1397/12/06

Registrant information

Name

Zohreh Poursaleh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7787 7434

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-16, 1397/04/25

Expected recruitment end date

2020-07-15, 1399/04/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of efficacy of "Monavvem" capsule comparing to placebo on the quality of sleep in patients with chronic insomnia

Public title

The effect of "Monavvem" capsule on chronic insomnia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion Criteria: Inclusion Criteria:Individuals aged 18 to 65 with the diagnosis of insomnia; ISI Score>7; no history of severe drug reaction to certain types of herbal medicines found in the drug; without using allopathic sleep aid medication in a week ago; Patients with the oral or written informed consent

Exclusion criteria:

Exclusion critria: Patients with uncontrolled and severe organic or psychiatric diseases as Parkinson's disease, Alzheimer's; alchohol or substance abuse; any other medication use or their withdrawal which affects sleep; history of blood coagulation disorders as thrombosis or emboli; other sleep disorders; pregnancy and lactation

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization block, individual, statistical software

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, major researcher, Data Collector

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Tavanir Cross.,Vanak Square,

City

Tehran

Province

Tehran

Postal code

1516745811

Approval date

2018-12-22, 1397/10/01

Ethics committee reference number

ECH.REC.1397.878

Health conditions studied

1

Description of health condition studied

Insomnia

ICD-10 code

G47.0

ICD-10 code description

Insomnia

Primary outcomes

1

Description

Severity Insomnia

Timepoint

Baseline, 4th week, 8th week

Method of measurement

severity index Insomnia (ISI)

2

Description

Sleep Quality

Timepoint

Baseline, 4th week, 8th week

Method of measurement

Sleep Quality Assessment (PSQI)

3

Description

Anxiety

Timepoint

Baseline, 4th week, 8th week

Method of measurement

Hamilton's Anxiety Rating Scale (HAM-A)

4

Description
Depression
Timepoint
Baseline, 4th week, 8th week
Method of measurement
Hamilton's Depression Scale (HAM-D)

Secondary outcomes

1

Description
Side effects
Timepoint
The end of study
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: Fourth 690 mg capsules of Monavvem capsule, two capsules at evening and two capsules at night (one hours before usual sleep time)
Category
Treatment - Drugs

2

Description
Control group: Fourth 690 mg capsule of Placebo, two capsules at evening and two capsules at night (one hours before usual sleep time)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiatallah Sleep clinic
Full name of responsible person
زهره پورصالح
Street address
Mulla Sadra St,. Vanak Square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Deputy Research and Technology
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Zohreh Poursaleh
Position
PhD Student
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
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Position

Associate professor

Latest degree

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Position

Student of PhD

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Other areas of specialty/work

Traditional Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No information

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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable