

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 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 socio-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; alcohol 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

zpoursaleh7@sbmu.ac.ir

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 criteria: Patients with uncontrolled and severe organic or psychiatric diseases as Parkinson's disease, Alzheimer's; alcohol 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

زهرة 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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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mina Movahhed

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Student of PhD

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Medical doctor

Other areas of specialty/work

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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