

# 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

##### City

Tehran

##### Province

Tehran

##### Postal code

1435916471

##### Phone

+98 21 2816 2314

##### Email

z\_poursaleh7@sbm.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Deputy Research and Technology

##### Street address

Velenjak

##### City

Tehran

##### Province

Tehran

##### Postal code

1435945811

##### Phone

+98 21 8877 3521

##### Email

z\_poursaleh7@sbm.ac.ir

#### 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

##### Street address

Tavanir Cross, South Valiasr Ave., Vanak squ

##### City

Tehran

##### Province

Tehran

##### Postal code

1435916471

##### Phone

+98 21 8877 3521

**Email**

z\_poursaleh7@sbmu.ac.ir

## 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**

Traditional Medicine

**Street address**

میدان ونک، خیابان ولیعصر جنوبی، تقاطع توانیر

**City**

Tehran

**Province**

Tehran

**Postal code**

1516745811

**Phone**

+98 21 8877 3521

**Email**

movahhedm54@gmail.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Zohreh Poursaleh

**Position**

Student of PhD

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Traditional Medicine

**Street address**

Tavanir Cross, South Valiasr St., Vanak Square

**City**

Tehran

**Province**

Tehran

**Postal code**

1516745811

**Phone**

+98 21 8877 3521

**Email**

z\_poursaleh7@sbmu.ac.ir

## 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