Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Effect of auricular vagus nerve stimulation on total sleep time, sleep quality, insomnia severity and sleep log in primary insomnia patients

Protocol summary

Study aim

Determining the effect of Vagus nerve stimulation on total sleep time, sleep quality, insomnia severity and sleep log in primary insomnia patients

Design

Parallel group randomized trial, double blinded and Sham controlled and 25 sample size

Settings and conduct

In this double blinded randomized clinical trial, we give insomnia patients taVNS intervention. After one week of completing sleep-log, patients get it for 4 weeks daily, with 20 Hz frequency and 2 times a day for 20 minutes. One electrode is attached to left ear concha and the other to the left shoulder. Questionaries and sleep log are measured at the beginning and the end of the study. Location of the intervention: We explain about the intervention and the device to the patients and the they do it in their house every day. Blinding: patients and people who involve in follow up and data gathering are blind. The researcher who explains intervention to the patient and knows the patient's group, does not cooperate in the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18 and 70, right-handed, diagnosed as primary insomnia with at least one of the symptoms of insomnia (1.problem with falling asleep, 2. problem with maintaining sleep, 3.sleep deprivation) for at least 3 months, PSQI sleep quality equal or more than 7 Exclusion criteria: History of head injury, Nervous system disorder, Drug abuse, Critical primary endocrine, cardiovascular, blood or psychiatry disease, Contraindications for taVNS intervention like asthma and cardiac arrhythmias, Use of hypnotic drugs, Use of psychiatric drugs, Pregnancy or lactation

Intervention groups

Intervention group: 25 people, electric stimulation in concha of the ear Control group: 25 people, electric stimulation in earlobe of the ear

Main outcome variables

duration of sleep, sleep quality ,fatigue and insomnia severity, depression and anxiety severity

General information

Reason for update

1. Changing sample size from 70 to 50 (Because of the number of available taVNS devices, which was lower than we thought, current sample size would make our study really long and frustrating that can make different kinds of biases) 2. Changing the Actigraphy outcome to sleep-log graph (Because of incomplete provision of Actigraphy devices with sufficient quality from the manufacturer company, we substituted it with sleep-log graph as another quantitive method for examining patients' daily sleep time) 3. Changing the location of electrodes in control group from margin of the ear to the earlobe (based on our latest literature review, earlobe is a more reliable region than ear margin for the control group)

Acronym

IRCT registration information

IRCT registration number: **IRCT20230812059131N1**
Registration date: **2023-09-24, 1402/07/02**
Registration timing: **prospective**

Last update: **2023-12-22, 1402/10/01**
Update count: **1**

Registration date

2023-09-24, 1402/07/02

Registrant information

Name

Arian Hasani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3660 1419

Email address

a-hasani@student.tums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-01-21, 1402/11/01
Expected recruitment end date
2025-01-20, 1403/11/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of auricular vagus nerve stimulation on total sleep time, sleep quality, insomnia severity and sleep log in primary insomnia patients

Public title
Effect of auricular vagus nerve stimulation on sleep
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 and 70 Being right-handed Being diagnosed as primary insomnia with at least one out of three symptoms of primary insomnia (1.problem with falling asleep, 2problem with maintaining sleep, 3.sleep deprivation) for at least 3 months PSQI sleep quality equal or more than 7
Exclusion criteria:
History of head injury Nervous system disorder Drug abuse Critical primary disease in endocrine system, cardiovascular system, blood and psychiatry Having contraindications for taVNS intervention like asthma and cardiac arrhythmias Use of hypnotic drugs Use of psychiatric drugs Pregnancy or lactation
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **25**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, allocation will be done into two groups of intervention and control. The tool of allocation will be "www.sealed envelope.com" and the ratio of allocation is 1:1. The type of allocation is complete (simple) and the unit of allocation is each patient.
Blinding (investigator's opinion)
Double blinded
Blinding description
Both patients and people who follow up the patients and retrieve their data, are blinded regarding the patient's intervention. In order to achieve this, the researcher who explains the patient how to use the device and knows the location of electrode and the group of each patient (control or intervention), does not cooperate in any of the future steps of the study like follow ups or data analysis.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Room 604, sixth floor, central building of Tehran university of medical sciences, Keshavarz Blvd, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1417614411
Approval date
2023-07-11, 1402/04/20
Ethics committee reference number
IR.TUMS.NI.REC.1402.016

Health conditions studied

1

Description of health condition studied
Primary Insomnia
ICD-10 code
F51.01
ICD-10 code description
A condition of unsatisfactory quantity and/or quality of sleep, which persists for a considerable period of time, including difficulty falling asleep, difficulty staying asleep, or early final wakening. Insomnia is a common symptom of many mental and phys

Primary outcomes

1

Description
Duration of sleep
Timepoint
Measuring sleep duration from the beginning till the end of the intervention (everyday for a month)
Method of measurement
sleep log chart

2

Description
Sleep quality
Timepoint
Measured in the beginning and the end of the study (beginning and end of the one month duration of the intervention)
Method of measurement
Pittsburgh Sleep Quality Index (PSQI) questionary

3

Description
Insomnia severity
Timepoint
Measured in the beginning and the end of the study (beginning and end of the one month duration of the intervention)
Method of measurement
Insomnia severity index (ISI)

4

Description
Fatigue severity
Timepoint
Measured in the beginning and the end of the study (beginning and end of the one month duration of the intervention)
Method of measurement
Epworth sleepiness scale (ESS)

5

Description
Depression severity
Timepoint
Measured in the beginning and the end of the study (beginning and end of the one month duration of the intervention)
Method of measurement
Hamilton Rating Scale for Depression (HAMD)

6

Description
Anxiety severity
Timepoint
Measured in the beginning and the end of the study (beginning and end of the one month duration of the intervention)
Method of measurement
Hamilton Rating Scale for Anxiety (HAMA)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this study, patients in intervention group receive electric stimulation in concha region of the ear (enervated by Vagus nerve). One electrode is placed in left ear concha in the form of a clip and the other one is placed behind the shoulder in the form of a pad.
Category
Treatment - Devices

2

Description
Control group: In this study, patients in control receive electric stimulation in earlobe region of the ear (non-enervated by Vagus nerve). One electrode is placed in left ear concha in the form of a clip and the other one is placed behind the shoulder in the form of a pad.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam khomeini hospital
Full name of responsible person
Hamed Amirifard
Street address
Imam khomeini hospital complex, Dr.Gharib St, Keshavarz Blvd, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
۱۴۱۹۷۳۳۱۴۱
Phone
+98 21 6694 8899
Fax
Email
Imamhospital@tums.ac.ir
Web page address
https://ikhc.tums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Neurology research center of Imam khomeini hospital

Full name of responsible person
Abbas Tafakhori

Street address
Imam khomeini hospital complex, Dr. Gharib St, Keshavarz Blvd, Tehran, Iran

City
Tehran

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Postal code
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Phone
+98 21 6694 8899

Email
Imamhospital@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Neurology research center of Imam khomeini hospital

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
Tehran University of Medical Sciences

Full name of responsible person
Arian Hasani

Position
Student of general medicine

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

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No 19, first alley, northern Naft St, mirdamad Blvd, Tehran, Iran

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Publishing the results of the study in the form of medical doctor thesis and a study in international journals

When the data will become available and for how long

After the defense session of the thesis

To whom data/document is available

For general population

Under which criteria data/document could be used

Other researchers

From where data/document is obtainable

Arian Hasani Address: No 19, First alley, Northern Naft St, Mirdamad, Tehran, Iran Email address: a-Hasani@student.tums.ac.ir Emergent number: +989390348543 Hamed Amiri fard Address: Neurology building, Northern door of Imam Khomeini hospital, Eastern Bagher khan St, Chamran highway, Tehran, Iran Email address: dr.amirifard@gmail.com Emergent number: 02161192053

What processes are involved for a request to access data/document

After confirmation by the responsible authorities

Comments