Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Efficacy of Nortriptyline in treating OSA: Randomized, placebo-controlled, double-blind clinical trial.

Protocol summary

Study aim

Observing the effect of nortriptyline on obstructive sleep apnea and its use in treating these patients, improving quality of life and preventing complications

Design

A Phase 3 Randomized Double-Blind Placebo-Controlled Parallel-Arm Study to Compare Nortriptyline to Placebo in 24 Obstructive Sleep Apnea.

Settings and conduct

Patients in the sleep test section of Masih Daneshvari Hospital undergo polysomnography (PSG) and are then divided into two groups by a researcher, receiving either medication or a placebo. One month later, PSG is performed again after medication use. The patient, technician, scorer, and treating physician are unaware of the medication use.

Participants/Inclusion and exclusion criteria

Patients with obstructive sleep apnea between the ages of 18 and 65, after undergoing polysomnography with an AHI greater than 15, an Epworth Sleepiness Scale (ESS) above 10, a body mass index (BMI) between 18 and 30 for men and 32 kg/m2 for women, who are unwilling to use a respiratory device, will be included in the study. Patients with known cardiac, renal, pulmonary, metabolic conditions and uncontrolled HTN or known neurological, muscular or psychiatric disorders, as well as those with insomnia or hypersomnia disorders, sleep behavior disorders, restless legs syndrome (RLS), shift work or night work occupations or use of stimulant or central nervous system depressant drugs will be excluded from the study.

Intervention groups

We divide the study into two groups: 1) Control group: a group that receives a placebo after polysomnography. 2) Intervention group: a group that receives 25 mg of nortriptyline after polysomnography. Polysomnography is repeated one month after medication use.

Main outcome variables

The apnea-hypopnea Index (AHI), the arousal index, the Epworth Sleepiness Scale (ESS), and the nighttime snoring level based on the Visual Analog Scale (VAS)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240407061441N1**
Registration date: **2024-04-18, 1403/01/30**
Registration timing: **registered_while_recruiting**

Last update: **2024-04-18, 1403/01/30**
Update count: **0**

Registration date

2024-04-18, 1403/01/30

Registrant information

Name

Fateme Mohammadi aniloo

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2224 2889

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-13, 1403/01/25

Expected recruitment end date

2024-07-22, 1403/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Efficacy of Nortriptyline in treating OSA: Randomized, placebo-controlled, double-blind clinical trial.

Public title
Efficacy of Nortriptyline in treating OSA

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
≥18 years of age at the time of informed consent PSG criteria: AHI of >5; ≤ 25% central or mixed apneas; and PLM arousal index ≤15 Escale of sleepiness symptom score ≥10 PAP intolerance or current PAP refusal BMI between 18.5 and 30 kg/m2 for men, or 32 kg/m2 for women

Exclusion criteria:
Narcolepsy, restless leg syndrome, REM sleep behavior disorder Insomnia disorder or use of sedative-hypnotics or other medication to treat or avoid insomnia symptoms, shift disorder or night shift craniofacial malformation syndrome, or grade ≥3 tonsillar hypertrophy Clinically significant cardiac disease, e.g., ventricular arrhythmia, untreated or unstable coronary artery disease, cardiac failure Metabolic, renal, pulmonary disease, and uncontrolled HTN Neuromuscular disorder (e.g., motor neuron disease, muscular dystrophy or myopathy, myasthenic syndrome); epilepsy; Parkinson's, Alzheimer's, or another neurodegenerative disease Central neural system stimulant or suppressant drugs

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
The participant does not know which treatment group he is in. The Care Provider and Outcomes Assessor do not know about the treatment performed.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Masih Daneshvari Teaching, Research, and Treatment Center for Tuberculosis and P

Street address
Floor 7, Emam Hasan Building, Masih Daneshvari Hospital, Daar-Abad, Niavaran

City
Tehran

Province
Tehran

Postal code
1956944413

Approval date
2024-03-05, 1402/12/15

Ethics committee reference number
IR.SBMU.NRITLD.REC.1402.238

Health conditions studied

1

Description of health condition studied
Obstructive Sleep Apnea

ICD-10 code
G47.33

ICD-10 code description
Obstructive sleep apnea (adult) (pediatric)

Primary outcomes

1

Description
Apnea-Hypopnea Index

Timepoint
after one month of medication consumption

Method of measurement
Polysomnography

2

Description
Sleepiness Scale

Timepoint
after one month of medication consumption

Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients are treated with Nortriptyline 25 mg for one month, and then undergo polysomnography.
Category
Treatment - Drugs

2

Description
Control group: Patients are treated with a placebo for one month and then undergo polysomnography.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Masih Daneshvari Hospital
Full name of responsible person
Fateme Mohammadi
Street address
Sleep Lab, Masih Daneshvari Hospital, Dar-abad, Niavaran
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Postal code
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fatemeh.Mohammadi.inloo@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Seyed Ali Ziai
Street address
Floor. 5, No. 2 ,Shahid Arabi Street ,Yemen Street, Chamran Expressway
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Postal code
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Phone
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Email
info@sbmu.ac.ir
Web page address
https://research.sbmu.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
Fateme Mohammadi
Position
Non-faculty specialist physician
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
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sleep Lab, Masih Daneshvari Hospital, Dar-abad, Niavaran
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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
Demographic data, drug/placebo consumption and study results will be published without mentioning the names of individuals.
When the data will become available and for how long
Access period will start six months after the publication of the results.
To whom data/document is available
Executives and collaborators of the project and research centers
Under which criteria data/document could be used
The data must not be published publicly.
From where data/document is obtainable
Chronic Disease Research Center, Dr. Fateme Mohammadi
What processes are involved for a request to access data/document
Sending an email to Dr. Fateme Mohammadi --> Review and approval by Dr. Fateme Mohammadi --> Sending information
Comments