Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Evaluating the effects of the Atomoxetine and Trazodone combination on the number of apneas and apnea-hypopnea sleep index in obstructive sleep apnea patients referred to the sleep clinic of Imam Khomeini hospital.

Protocol summary

Study aim
Defining the effects of combination therapy with atomoxetine and trazodone on the number of respiratory arrests and on apnea-hypopnea indices in patients with obstructive sleep apnea

Design
Cross-over clinical trial, double-blind, randomized, phase 2-3, on 18 patients

Settings and conduct
Imam Khomeini Hospital Complex's Sleep Disorders Center In order to randomize, the random block method has been used. Patients are randomly divided into two groups, A and B, with equal numbers. In the first session, group A receives the placebo half an hour before bedtime and group B receives the study drug half an hour before bedtime, and in the second session, group A receives the study drug half an hour before bedtime and group B receives the placebo half an hour before bedtime.

Participants/Inclusion and exclusion criteria
Inclusion criteria : medical history of obstructive sleep apnea with an 15<AHI on the last polysomnogram, age between 18 and 65, incompatibility with CPAP or BiPAP treatment, not being a candidate for surgery or not wanting surgery, and not being able to use CPAP or BiPAP. Exclusion criteria: Existence of any commodities (except controlled blood pressure, hyperlipidemia and diabetes), Existence of any underlying heart disease, pregnancy, sensitivity to the drugs used in the study, use of any drug that leads to changes in the physiology of respiration, sleep/wake and muscles, inability to sleep in a supine position

Intervention groups
Each patient will treated once with a combination of 80 mg of atomoxetine and 50 mg of trazodone and once with placebo.

Main outcome variables
Improve sleep quality and reduce sleep apnea and hypopnea attacks

General information

Reason for update
Registering the completion of Patient recruitment and completion of the trial

Acronym

IRCT registration information
IRCT registration number: **IRCT20220607055095N1**
Registration date: **2022-06-26, 1401/04/05**
Registration timing: **prospective**

Last update: **2023-07-24, 1402/05/02**
Update count: **3**

Registration date
2022-06-26, 1401/04/05

Registrant information

Name
Mojtaba Shahbazi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-06, 1401/04/15

Expected recruitment end date
2023-08-23, 1402/06/01
Actual recruitment start date
2022-07-06, 1401/04/15
Actual recruitment end date
2022-12-22, 1401/10/01
Trial completion date
2023-01-21, 1401/11/01

Scientific title
Evaluating the effects of the Atomoxetine and Trazodone combination on the number of apneas and apnea-hypopnea sleep index in obstructive sleep apnea patients referred to the sleep clinic of Imam Khomeini hospital.

Public title
Effects of Atomoxetine and Trazodone combination in obstructive sleep apnea
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Definite diagnosis of obstructive sleep apnea in medical history with AHI>15 in polysomnography lack of compliance treatment with CPAP or BIPAP either the patient is unwilling to have surgery or they are not candidates for surgery in the opinion of the expert
Exclusion criteria:
commodities' existence (excluding controlled blood pressure, hyperlipidemia and diabetes) any underlying cardiac disease, such as arrhythmia that is seen on the ECG History of seizures, Panic disorder, Hyperventilation syndrome, Attention Deficit Hyperactivity Disorder, Autism Spectrum Disorder Hypersensitivity to lidocaine, atomoxetine or trazodone, substances used in placebo Taking any medication that leads to changes in the physiology of breathing, sleep / wake and muscles Taking any medication that leads to changes in the physiology of breathing, sleeping / waking and muscles Inability to sleep in supine position Pregnancy
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **18**
Actual sample size reached: **18**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to randomize, the random block method has been used. In this method, blocks of 4, 6 and 8 are used. Patients are randomly divided into two groups A and B with equal numbers. In the first session, group A receives the placebo half an hour before bedtime and group B receives the study drug half an hour before bedtime, and in the second session, group A receives the study drug half an hour before bedtime and group B receives placebo half an hour before bedtime.
Blinding (investigator's opinion)
Double blinded
Blinding description
The patient does not know in which treatment group he is. The data analyzer does not know about the treatment performed.
Placebo
Used
Assignment
Crossover
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
Imam Khomeini Hospital Complex ,Dr. Gharib Street ,Keshavarz Boulevard ,Tehran
City
Tehran
Province
Tehran
Postal code
1419733141
Approval date
2022-03-15, 1400/12/24
Ethics committee reference number
IR.TUMS.IKHC.REC.1401.002

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

medication Night

Method of measurement

Polysomnography

Secondary outcomes

1

Description

safety

Timepoint

The morning after taking the drug

Method of measurement

asking the patient

Intervention groups

1

Description

Intervention group: Patients are treated with 80 mg of atomoxetine (Mofid company) and 50 mg of trazodone (Razak company) once half an hour before the polysomnography test and then undergo polysomnography overnight.

Category

Treatment - Drugs

2

Description

Control group: Patients are treated with placebo once half an hour before the polysomnography test and then undergo polysomnography overnight.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital complex

Full name of responsible person

Hamed Amirifard

Street address

Imam Khomeini Hospital Complex ,Dr. Gharib Street ,Keshavarz Boulevard ,Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotuhi

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Vice Chancellor for Research and Technology, sixth floor , Central Tehran University of medical sciences Organization , corner of Quds Street , Keshavarz Boulevard

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Hamed Amirifard

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Neurology

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Not applicable