

# 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  $15 < \text{AHI}$  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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8601 3770

##### Email address

mojtaba.shahba94@gmail.com

#### 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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Tehran

#### Province

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#### Postal code

1419733141

#### Phone

+98 21 6694 8899

#### Email

Imamhospital@tums.ac.ir

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Akbar Fotuhi

#### Street address

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

#### City

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#### Postal code

1417653761

#### Phone

+98 21 8163 3685

#### Email

vcr@tums.ac.ir

#### Web page address

<https://vcr.tums.ac.ir/>

### 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

### Contact

**Name of organization / entity**  
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Hamed Amirifard  
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Assistant Professor  
**Latest degree**  
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**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

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Tehran University of Medical Sciences

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Mojtaba Shahbazi  
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Resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Neurology  
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mojtaba.shahba94@gmail.com

## 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