

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### Evaluating the effect of Atomoxetine and Oxybutynin combination on the number of apnea in obstructive sleep apnea patients

#### Protocol summary

##### Study aim

As the efficiency of Atomoxetine and Oxybutynin combination observed, It can be prescribed for OSA patients in order to promote their quality of life and prevent the consequences.

##### Design

Crossover, double-blind, placebo-controlled, randomized phase III clinical trial on 18 patients. In order to randomize, patients are allocated in 4-person blocks(block-randomization)

##### Settings and conduct

Occupational Sleep Research Center - Iranian Center of Neurological Research Polysomnography (PSG): PSG consists of electroencephalography (EEG), electrooculography (EOG), electrocardiography (ECG), and electromyography (EMG) which is used for diagnosis of OSA and determination of the disease severity. Snoring, arterial blood oxygen saturation, respiratory airflow, and respiratory effort were monitored during night sleep. Some of our parameters like RDI, mean O<sub>2</sub> saturation (mean SaO<sub>2</sub>), and minimum O<sub>2</sub> saturation (nadir SaO<sub>2</sub>) during over-night sleep were obtained from PSG test

##### Participants/Inclusion and exclusion criteria

Inclusion criteria established OSA diagnosis with AHI more than 20 age between 21 and 65 years old noncompliant for CPAP or BiPAP not indicated for surgical treatment Exclusion criteria the existence of any other disorders(except HTN, Hyperlipidemia and Diabetes) Claustrophobia Inability for being in supine position Allergy to any of lidocaine, atomoxetine, oxybutynin, vitamin C pregnancy Any disease that exacerbates by antimuscarinic drugs

##### Intervention groups

The sample will be divided into two groups: 1)placebo group: consume placebo(vitamin C) 30 minutes prior to polysomnography 2) intervention group: consume Atomoxetine and Oxybutynin combination 30 minutes prior to polysomnography. After a week, each group will

consume the other drug.

##### Main outcome variables

AHI; apnea index; hypopnea index; nadir o<sub>2</sub>sat; mean o<sub>2</sub>sat; arousal index; WASO; sleep onset latency; total sleep time

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220201053905N1**

Registration date: **2022-06-08, 1401/03/18**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-06-08, 1401/03/18**

Update count: **0**

##### Registration date

2022-06-08, 1401/03/18

##### Registrant information

##### Name

Hamed KhoshAkhlagh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 5546 0184

##### Email address

hamed.khoshakhlagh@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-04-04, 1401/01/15

##### Expected recruitment end date

2023-10-07, 1402/07/15

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Evaluating the effect of Atomoxetine and Oxybutynin combination on the number of apnea in obstructive sleep apnea patients

**Public title**  
Evaluating the effect of Atomoxetine and Oxybutynin combination on the number of apnea in obstructive sleep apnea patients referring to the sleep clinics of Tehran University of Medical Sciences

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
established OSA diagnosis in the past medical history with AHI more than 20 in the last polysomnography(if accessible) age between 21 and 65 years old noncompliant for CPAP or BiPAP not indicated for surgical treatment, according to the sleep specialist. or the situation that the patient doesn't tend to surgical treatment  
**Exclusion criteria:**  
the existence of any other disorders(except controlled HTN, Hyperlipidemia and Diabetes) the consumption of any drug resulting in changes in ventilation physiology, sleep/awake cycle and the muscles; such as methocarbamol, tramadol, TCAs, SSRIs, SNRIs, ventilation stimulants and depressants, hypnotics, CNS stimulants, central sleep apnea, and etc. Claustrophobia Inability for being in supine position Allergy to any of lidocaine, atomoxetine, oxybutynin, vitamin C the existence of any underlying heart diseases such as arrhythmias the consumption of psychiatric drugs such as atomoxetine or any other drug that is prescribed for medical care and could not be withdrawn while the experiment night. for women: pregnancy the history of seizure, panic disorder, hyperventilation syndrome, ADHD, ASD Any disease that exacerbates by antimuscarinic drugs such as urinary retention, BPH, severe ulcerative colitis, glaucoma, myasthenia gravis

**Age**  
From **21 years** old to **65 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**  
Target sample size: **18**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
block-randomization, each block includes 4 persons: We

will pick up 4 persons and put them in one of the placebo or intervention group in regard to the gender composition. Thus, We will pick 4 other persons up and put them in two groups in a same way. This block-randomization continues until all 18 persons been put in a group.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

patients, nurses and patient's relatives would not aware of what the drug exactly is. So the participant would not find out that the prescribed compound is whether Ato-Oxy or placebo. It leads the participant to imagine the placebo's effect equal to Ato-Oxy's, so at the end of the study, the placebo effect could be ruled out.

**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**

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafshan & South Falamak, Qods Town, Tehran, Iran.

**City**

Tehran

**Province**

Tehran

**Postal code**

1467664978

**Approval date**

2022-04-03, 1401/01/14

**Ethics committee reference number**

IR.TUMS.FNM.REC.1401.001

**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

AHI(Apnea-Hypopnea index): Number of apnea plus hypopnea during a night sleep per hour

### Timepoint

Just after intervention

### Method of measurement

Polysomnography records

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group: This group will consume Oxybutynin-Atomoxetine combination during the first night of study, then they would consume placebo(Vitamin C) at least 1 week later.

### Category

Treatment - Drugs

## 2

### Description

Control group: This group will consume placebo(Vitamin C) during the first night of study, then they would consume Oxybutynin-Atomoxetine combination at least 1 week later.

### Category

Placebo

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Baharloo Hospital

#### Full name of responsible person

Arezu Najafi

#### Street address

Occupational Sleep Research Center, Baharloo Hospital, Behdari square, RahAhan Square

#### City

Tehran

#### Province

Tehran

#### Postal code

1339973111

#### Phone

+98 21 5546 0184

#### Email

osrc@tums.ac.ir

## 2

### Recruitment center

#### Name of recruitment center

Imam Khomeini Hospital Complex

#### Full name of responsible person

Hamed AmiriFard

#### Street address

Fourth Floor, Iranian Center of Neurological Research Building, Imam Khomeini Hospital, Keshavarz Blvd., Tehran, Iran.

#### City

Tehran

#### Province

Tehran

#### Postal code

1419733141

#### Phone

+98 21 6119 2398

#### Email

icnr@tums.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Dr. Akbar Fotouhi

#### Street address

Sixth Floor, Office of Research and Technology, The headquarters of Tehran University of Medical Sciences, Cross of Keshavarz Blvd. and Qods Street , Keshavarz Blvd., Tehran, Iran.

#### City

Tehran

#### Province

Tehran

#### Postal code

1417653757

#### Phone

+98 21 8163 3698

#### Email

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**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Neurology

**Street address**

Fourth Floor, Iranian Center of Neurological Research Building, Imam Khomeini Hospital, Keshavarz Blvd., Tehran, Iran.

**City**

Tehran

**Province**

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**Postal code**

1419733141

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+98 21 6119 2398

**Email**

dr.amirifard@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Hamed AmiriFard

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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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**

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**

The demographic data, drug/placebo consumption before intervention and defined outcomes will be evaluated. All data will be published without noticing the participants' names.

**When the data will become available and for how long**

The data will become available in 18 months later.

**To whom data/document is available**

The participants' data is secured and available just for primary researcher(s), collaborators and the research centers the study is going to be conducted in.

**Under which criteria data/document could be used**

The data must not be published publicly.

**From where data/document is obtainable**

Iranian Center of Neurological Research, Dr Hamed AmiriFard

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

To send email to Dr. AmiriFard or other researchers and clarifying the request and its purpose --> To review admissibility of the request by the researchers --> Final approval by Dr. AmiriFard --> To send the data for

requester in a week to a month after the request.

**Comments**