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 O2 saturation (mean SaO2), and minimum O2 saturation (nadir SaO2) 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 o2sat; mean o2sat; 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

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Iran (Islamic Republic of)

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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 Zarafashan & 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 weak 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 weak 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
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2

Recruitment center
Name of recruitment center
Imam Khomeini Hospital Complex
Full name of responsible person
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Fourth Floor, Iranian Center of Neurological Research Building, Imam Khomeini Hospital, Keshavarz Blvd., Tehran, Iran.
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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.
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1417653757
Phone
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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.

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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)
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 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 it's 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