

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

pilot study of medium term effects of Trazodone and Atomoxetine combination on the number of apnea and apnea-hypopnea sleep index in obstructive sleep apnea patients

Protocol summary

Study aim

Defining the medium term 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

non randomised, non blinded clinical trial without control group on 18 patients

Settings and conduct

After recruitment, patients referred to the sleep clinic of Imam Khomeini Hospital are treated with the combination of atomoxetine and trazodone for one month, and after that they undergo polysomnography.

Participants/Inclusion and exclusion criteria

Inclusion criteria: medical history of obstructive sleep apnea with an AHI of 15 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

All included patients are treated for one month with the combination of atomoxetine 40 mg and Trazodone 50 mg.

Main outcome variables

Improve sleep quality and reduce sleep apnea and hypopnea attacks

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220607055095N2**

Registration date: **2023-07-19, 1402/04/28**

Registration timing: **prospective**

Last update: **2023-07-19, 1402/04/28**

Update count: **0**

Registration date

2023-07-19, 1402/04/28

Registrant information

Name

Mojtaba Shahbazi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

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

pilot study of medium term effects of Trazodone and

Atomoxetine combination on the number of apnea and apnea-hypopnea sleep index in obstructive sleep apnea patients

Public title

study of medium term effects of Trazodone and Atomoxetine combination in obstructive sleep apnea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Definite diagnosis of obstructive sleep apnea 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) 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 any underlying cardiac disease, such as arrhythmia Inability to sleep in supine position Hypersensitivity to lidocaine, atomoxetine or trazodone Pregnancy History of seizures, Panic disorder, Hyperventilation syndrome, Attention Deficit Hyperactivity Disorder, Autism Spectrum Disorder any hepatic disease or failure

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **18**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

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

2023-06-20, 1402/03/30

Ethics committee reference number

IR.TUMS.IKHC.REC.1402.111

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 on month medication consumption

Method of measurement

Polysomnography

Secondary outcomes

1

Description

minimum O2 saturation

Timepoint

once

Method of measurement

pulse oxymetry

Intervention groups

1

Description

Intervention group: All patients are treated with a combination of atomoxetine and trazodone for one month, and then undergo polysomnography.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital complex

Full name of responsible person

Arezu Najafi

Street address

Imam Khomeini Hospital Complex ,Dr. Gharib Street
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

اکبر فتوحی

Street address

Keshavarz Blvd, Ghods Avene, Ghods building

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vcr@sina.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

Arezu Najafi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Occupational Medicine

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Latest degree

Subspecialist

Other areas of specialty/work

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Position

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Latest degree

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Neurology

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Email

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

Undecided - It is not yet known if there will be a plan to make this available