

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

Assessment of Treatment Effect on Brain Structural, Functional and Metabolic Changes in Obstructive Sleep Apnea Syndrome Using Magnetic Resonance Imaging

Protocol summary

Study aim

Use non-invasive MRI to evaluate the effectiveness of CPAP treatment after a period of six months and help decide whether to continue or discontinue treatment (and replace it with other treatments)

Design

Clinical trial, with single, non-blind, non-random grouping, on 12 patients.

Settings and conduct

After performing a sleep test at Imam Khomeini Hospital, MRI will be taken in the National Brain Mapping Laboratory.

Participants/Inclusion and exclusion criteria

The Sleep Disorders Fellowship identifies patients using the facilities available in the Sleep Clinic, in particular the PSG device, and introduces them to the researcher after receiving their informed written consent. The output parameters of the PSG are also made available to the researcher. Patients with the following conditions are excluded from the study: A) People who have a background of respiratory disease (other than apnea). B) People with a history of malignancy. C) People with a history of cardiovascular disease. D) People with a history of neurological diseases (such as neurodegenerative diseases, epilepsy and head trauma). E) People who abuse alcohol or drugs or take psychotropic drugs while studying. F) People who have structural lesions in the brain. G) People who, in addition to obstructive sleep apnea, also have hypoventilation syndrome. H) People with metabolic diseases (e.g. polycythemia). I) Patients who, after PSG and clinical tests, are diagnosed as not candidates for CPAP treatment. J) Patients whose image quality is low, for example, their image has a motion artifact due to shaking. K) People who have contraindications to MRI scans (such as people with cardiac pacemakers and metal implants or even people with Claustrophobia).

Intervention groups

Patients with sleep apnea syndrome who are treated with CPAP

Main outcome variables

Cortical Thickness, rsFC, OEF

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220410054475N1**

Registration date: **2022-04-13, 1401/01/24**

Registration timing: **prospective**

Last update: **2022-04-13, 1401/01/24**

Update count: **0**

Registration date

2022-04-13, 1401/01/24

Registrant information

Name

Mahdi Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 6690 7519

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mohammadi_ma@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-21, 1401/05/30

Expected recruitment end date

2024-05-18, 1403/02/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of Treatment Effect on Brain Structural, Functional and Metabolic Changes in Obstructive Sleep Apnea Syndrome Using Magnetic Resonance Imaging

Public title

Assessment of Treatment Effect on Brain Changes in Obstructive Sleep Apnea Syndrome Using MRI

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who have been diagnosed with obstructive sleep apnea syndrome after a sleep test.

Exclusion criteria:

People who have a background of respiratory disease (other than apnea). People with a history of malignancy. People with a history of cardiovascular disease. People with a history of neurological diseases (such as neurodegenerative diseases, epilepsy and head trauma). People who abuse alcohol or drugs or take psychotropic drugs while studying. People who have structural lesions in the brain. People who, in addition to obstructive sleep apnea, also have hypoventilation syndrome. People with metabolic diseases (such as polycythemia). Patients who, after PSG and clinical tests, are diagnosed as not candidates for CPAP treatment. People who have contraindications to MRI scans (such as people with cardiac pacemakers and metal implants or even people with a fear of closed space (Claustrophobia)).

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **12**

More than 1 sample in each individual

Number of samples in each individual: **3**

MR imaging findings in three stages: before treatment, one day after treatment and 6 months after treatment

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 (Faculty of Medicine)

Street address

Poursina Street

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Tehran

Province

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Postal code

1417613151

Approval date

2022-02-21, 1400/12/02

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.1404

Health conditions studied**1****Description of health condition studied**

Obstructive Sleep Apnea (OSA)

ICD-10 code

G47.33

ICD-10 code description

Obstructive sleep apnea (adult) (pediatric)

Primary outcomes**1****Description**

Brain Cortical Thickness

Timepoint

Before treatment, 6 months after treatment

Method of measurement

Analysis of structural MR images

2**Description**

Functional connection of brain areas (rsFC)

Timepoint

Before treatment, 6 months after treatment

Method of measurement

Analysis of functional MR images

3**Description**

Oxygen Extraction Fraction (OEF)

Timepoint

Before treatment, 6 months after treatment

Method of measurement

Analysis of structural MR images

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with obstructive sleep apnea syndrome who are treated with CPAP device. Control group: Healthy people (no obstructive sleep apnea syndrome) without intervention

Category

Treatment - Devices

Recruitment centers

1

Recruitment center**Name of recruitment center**

Imam Khomeini Hospital Complex

Full name of responsible person

Dr. Shahram Samadi

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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

Dr. Akbar Fotouhi

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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

Dr. Mohammad Ali Oghabian

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Physics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Person responsible for updating data

Contact

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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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available