Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Iran (Islamic Republic of)

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+98 21 6690 7519

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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
City
Tehran
Province
Tehran
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
Street address
Dr. Gharib Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
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1417653761
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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
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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