

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

The effect of Mandibular Advancement Splint in comparison with Sham device on apnea hypopnea index in mild to moderate obstructive sleep apnea

Protocol summary

Summary

In this study, 50 patients who had inclusion criteria were selected from patients suffering mild to average OSAS who referred to sleep clinic of Mashhad Ibn-Sina hospital. After explaining the objectives of the research and obtaining patients conscious consent to cooperate, they were included in the study. Patients were divided into two intervention and control groups using blocking random sampling. All patients received initial examination and medical records including photography, radiography, and waxing records. Then impression from mandible and maxilla was done with Alginate material from Materials-Kohler-Germany. In intervention group a record of jaws relation was taken while the patient was protruding lower jaw and in the next step, Essix clear device was made by Biostar machine according to patient's cast in the laboratory. Afterward, the Mandibular Advancement Splint was prepared based on the record of jaws. In order to prepare oral device, plate 3A and cold cure acrylic resin Acropars_Marlik-Iran were used. Control group also used placebo (oral device without jaw protrusion). Then for each patient in intervention group, pharyngeal MRI and pharyngeal volumetric were done twice, immediately with and without device. Since no pharyngeal anatomic changes happened by placebo, MRI was not performed in control group. After using devices by patients, daily sleepiness and sleep quality were evaluated by questionnaires at the beginning and one month after using the device. At last the results, MRI volumetric and possible side effects were compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014071618509N1**

Registration date: **2015-07-06, 1394/04/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-07-06, 1394/04/15

Registrant information

Name

Mina sadat Mohajerzadeh Heidari

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research and technology affairs of Mashhad University of Medical Sciences (MUMS)

Expected recruitment start date

2014-12-01, 1393/09/10

Expected recruitment end date

2016-01-02, 1394/10/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Mandibular Advancement Splint in

comparison with Sham device on apnea hypopnea index in mild to moderate obstructive sleep apnea

Public title

Oral device for treatment of obstructive sleep apnea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age more than 18 years, Willing to participate in the study, Having mild to moderate obstructive sleep apnea (Apnea Hypopnoea Index of 5 to 30), Having enough marginal dental adaptation Exclusion criteria: Having Periodontal or other kind of oral cavity disease, Having contraindication for cephalometry (such as pregnancy), Having Advanced temporomandibular joint disease, Having contraindication for body MRI

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

In order to matching intervention and control groups, we used Strata method. In this way man and woman Strata are used. Because most of the patients are middle-aged, age Strata not defined. Then control and intervention group allocated accidentally.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences.

Street address

Ghoreishi Building , Daneshgah St.

City

Mashhad

Postal code

Approval date

2014-11-01, 1393/08/10

Ethics committee reference number

922805-10/08/1393

Health conditions studied

1

Description of health condition studied

obstructive sleep apnea

ICD-10 code

G47.3

ICD-10 code description

Sleep apnoea

Primary outcomes

1

Description

Apnea Hypopnea Index per hours during sleep

Timepoint

before intervention and 1 month after intervention

Method of measurement

polysomnography

Secondary outcomes

1

Description

Oropharyngeal volumetry

Timepoint

at the beginning, with and without Mandibular Advancement Splint in interventional group

Method of measurement

Oropharyngeal MRI

2

Description

sleep quality and daytime sleepiness

Timepoint

before intervention and 1 month after intervention in interventional and control groups

Method of measurement

sleep quality questionnaire

Intervention groups

1

Description

Using advanced mandible splint with jaw protrusion in intervention group so that a record of jaws relation is taken while the patient is protruding lower jaw and in the next step Essix clear device is made by Biostar machine according to patient's cast in the laboratory. Afterward, the Mandibular Advancement Splint is prepared based on the record of jaws. In order to prepare oral device, plate 3A and cold cure acrylic resin Acropars_Marlik-Iran are used.

Category

Treatment - Devices

2**Description**

placebo device (oral device without jaw protrusion) in control group

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Mashhad chronic obstructive pulmonary disease research center

Full name of responsible person

Mahnaz Amini

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2**Recruitment center****Name of recruitment center**

Ebn -e- Sina Hospital Sleep Clinic

Full name of responsible person

Hadi Asadpour

Street address**City**

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3**Recruitment center****Name of recruitment center**

Mashhad Radiology research center

Full name of responsible person

Behrooz Zandi

Street address**City**

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for Research, Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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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

Vice Chancellor for Research, Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

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

Mashhad University of Medical Sciences

Full name of responsible person

Mahnaz Amini

Position

Assistant Professor , Internal Medicine Specialist , Pulmonary and Critical Care Subspecialist

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty