

Measuring muscle function in patients with obstructive sleep apnea

Submission date 02/11/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 14/11/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 13/11/2024	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Obstructive sleep apnoea (OSA) is a condition where the walls of the throat relax and narrow or close during sleep. Myofunctional therapy (MT) is a recent treatment option for OSA that involves orofacial (mouth and face) muscle training. However, few OSA guidelines include myofunctional assessment routinely during the examination at the Ear, Nose & Throat (ENT) office. This study aims to present the researchers' protocol for the examination of OSA adult patients, with a special interest in myofunctional evaluation.

Who can participate?

Patients aged 18 years and over who are scheduled for septoplasty (surgery to straighten the nasal septum) to screen for OSA

What does the study involve?

Once the routine ENT exam is done, the myofunctional exam includes measurements of lip sealing (how lips are closed during breathing), the lingual frenulum (tongue-tie that limits tongue movements), and the strength of the tongue and mouth muscles.

What are the possible benefits and risks of participating?

The main benefits for participants will be to receive an OSA diagnosis and myofunctional treatment. Few risks are expected, only related to a longer exam during the ENT consultation.

Where is the study run from?

Hospital Universitario de Fuenlabrada (Spain)

When is the study starting and how long is it expected to run for?

September 2021 to May 2025

Who is funding the study?

Hospital Universitario de Fuenlabrada (Spain)

Who is the main contact?

Prof. Guillermo Plaza, guillermo.plaza@salud.madrid.org

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

Prof Guillermo Plaza

ORCID ID

<https://orcid.org/0000-0001-6409-4921>

Contact details

Camino del Molino, 2

Fuenlabrada

Spain

28005

+34 (0)679472218

guillermo.plaza@salud.madrid.org

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

21/65

Study information

Scientific Title

Myofunctional evaluation as a part of the diagnosis of obstructive sleep apnea

Acronym

MF-OSA

Study objectives

Myofunctional therapy is a recent treatment option for obstructive sleep apnea (OSA). Examination of OSA adult patients should include myofunctional evaluation.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 14/12/2021, Hospital Universitario de Fuenlabrada Ethics Committee (Camino del Molino, 2, Fuenlabrada, 28042, Spain; +34 (0)916006600; ceic.hflr@salud.madrid.org), ref: 21/65

Study design

Prospective non-randomized study

Primary study design

Observational

Study type(s)

Diagnostic, Screening

Health condition(s) or problem(s) studied

Obstructive sleep apnea (OSA)

Interventions

ENT office exam, polysomnography and myofunctional evaluation including breathing type, lip sealing, lingual frenulum and evaluation of muscle strength of the lingual and oral muscles with the IOPI.

Intervention Type

Other

Primary outcome(s)

Polysomnography assessed with the Apnea-Hypopnea Index (AHI), with mild OSA defined as >5 events/h of sleep, moderate OSA as 15–29.9 events/h of sleep, and severe OSA as ≥ 30 events/h of sleep at one timepoint

Key secondary outcome(s)

The following secondary outcome measures are assessed at one timepoint:

1. Anatomical findings in the upper airway from the nasal valve area to the larynx:
 - 1.1. Friedman tonsil grading, scaled from 1 to 5
 - 1.2. Height of the hard palate, measured in centimeters
 - 1.3. Friedman tongue position (FTP), scaled from 1 to 5
 - 1.4. Mallampati scales, scaled from 1 to 5
 - 1.5. Basilingual hypertrophy assessed with lingual tonsil hypertrophy (LTH) Friedman classification, scaled from 1 to 5
 - 1.6. Awake dynamic exam with Müller maneuver, considered collapsed or not
2. Myofunctional exam:
 - 2.1. Breathing (nasal or oral)
 - 2.2. Lingual sealing (opened or closed)
 - 2.3. Lingual frenulum assessed using the Marchesani protocol (present or not)
 - 2.4. Muscle strength evaluated with the Iowa Oral Performance Instrument (IOPI) in KiloPascals at buccinator and tongue propulsion

Completion date

05/05/2025

Eligibility

Key inclusion criteria

Adult patients scheduled for septoplasty evaluated to screen for OSA at the Otorhinolaryngology Department

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

80 years

Sex

All

Key exclusion criteria

1. Systemic disease with a known inflammatory state
2. Presence of a muscle rehabilitation treatment
3. Previous nasal surgery
4. Previous OSA treatment (CPAP, surgery, or mandibular advancement device)

Date of first enrolment

05/11/2023

Date of final enrolment

05/12/2024

Locations**Countries of recruitment**

Spain

Study participating centre

Hospital universitario de Fuenlabrada

Camino del Molino, 2

Fuenlabrada

Spain

28005

Sponsor information**Organisation**

Hospital Universitario de Fuenlabrada

ROR

<https://ror.org/04scbtr44>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Hospital Universitario de Fuenlabrada

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Prof. Guillermo Plaza (guillermo.plaza@salud.madrid.org)

IPD sharing plan summary

Available on request