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Measuring muscle function in patients with obstructive sleep apnea

Submission date
02/11/2024

Recruitment status
No longer recruiting

Registration date
14/11/2024

Overall study status
Completed

Last Edited
13/11/2024

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 & Thorat (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

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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
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Spain
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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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes