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Validation of a low cost manometer to evaluate upper airway oropharyngeal muscle strength

Submission date
04/05/2025

Recruitment status
Recruiting

Registration date
06/05/2025

Overall study status
Ongoing

Last Edited
06/05/2025

Condition category
Ear, Nose and Throat

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Obstructive Sleep Apnea-Hypopnea Syndrome (OSAHS) is a condition where people experience repeated episodes of blocked breathing during sleep. This can lead to snoring, poor sleep quality, daytime sleepiness, and increased risk of heart problems. The most effective treatment is Continuous Positive Airway Pressure (CPAP), but not everyone sticks with it. This study aims to find out if using certain tools to measure muscle strength in the mouth and throat can help improve treatment for OSAHS.

Who can participate?
Adults aged 18 to 75 who have been diagnosed with moderate to severe OSAHS and have not received any prior treatment can participate. Healthy adults with good sleep habits and no complaints of snoring or daytime sleepiness can also participate as control subjects.

What does the study involve?
Participants will undergo various tests to measure the strength of their mouth and throat muscles using tools like the IOPI device, a digital manometer, and a digital spoon. They will also complete questionnaires about their sleep and muscle function. These tests will be done during a single visit to the hospital.

What are the possible benefits and risks of participating?
There are no expected side effects or complications from participating in this study. The tests are routine assessments commonly done in speech therapy and dysphagia units. Participants may benefit from gaining a better understanding of their condition and contributing to research that could improve treatment for OSAHS.

Where is the study run from?
Quirónsalud Hospital in Marbella and Hospital Campo de Gibraltar (Spain)

When is the study starting and how long is it expected to run for?
January 2025 to April 2026

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Carlos O'Connor, carlos.oconnor@quironsalud.es

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr Carlos O'Connor-Reina

ORCID ID
http://orcid.org/0000-0002-1670-4235

Contact details
Hospital Quironsalud Marbella, avda severo ochoa 22
Marbella
Spain
29603
+34 952780540
carlos.oconnor@quironsalud.es

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
AWGAP-2024-2

Study information

Scientific Title
Validation of the OMES questionnaire compared to objective measurement of oropharyngeal muscle tone using the IOPI manometer, Sandway manometer, and digital spoon

Acronym
LCTM

Study objectives

The use of the OMES questionnaire can be complemented by the values obtained through measurement instruments such as the IOPI device, digital manometer, and digital spoon.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/03/2025, CEIm Provincial de Málaga (Hospital Regional Universitario Carlos Haya. Avda Carlos Haya 84. Pabellon a.Hospital General 7 planta, Malaga, 29010, Spain; +34 951291977; eticainvestiga.hch.sspa@juntadeandalucia.es), ref: SICEIA-2024-002767

Study design
Prospective controlled quasi-experimental pilot study

Primary study design
Observational

Secondary study design
Comparative diagnostic validation study

Study setting(s)
GP practice, Hospital

Study type(s)
Prevention, Quality of life, Screening

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Obstructive sleep apnea

Interventions
Participants are enrolled after signing informed consent and screened to confirm eligibility (OSAHS diagnosis for cases; good sleep hygiene and absence of symptoms for controls). The study consists of a single evaluation visit taking place during the same week as the patient’s sleep study. During this visit, participants complete the OMES questionnaire and undergo muscle tone assessments using the IOPI® manometer, Sandway® manometer, and a digital spoon. All tests are performed by a trained speech therapist and recorded for later blinded assessment. The total duration of observation is approximately 1 hour. There is no longitudinal follow-up; data collection is completed in a single session.

Intervention Type
Other

Primary outcome measure
Orofacial muscle function measured using the OMES questionnaire at baseline (single visit).

Secondary outcome measures

1. Tongue and buccinator muscle strength measured using the IOPI® manometer at baseline (single visit). Measured in kilopascals (kps).
2. Tongue pressure measured using the Sandway® manometer at baseline (single visit). Measured in kilopascals (kps).
3. Tongue strength measured using a digital spoon at baseline (single visit). Measured in gr/cm².
4. Correlation between OMES score and values obtained by IOPI®, Sandway®, and digital spoon, analyzed at baseline (single visit)

Overall study start date
30/01/2025

Completion date
30/04/2026

Eligibility

Key inclusion criteria
Cases:
1. Age between 18 and 75 years
2. Diagnosis of moderate to severe OSAHS (AHI >15) with no previous treatment experience
3. No prior treatment for OSAHS
4. Signed informed consent (IC)

Controls:
1. Adequate sleep hygiene
2. No complaints of snoring
3. No complaints of daytime sleepiness
4. Epworth Sleepiness Scale < 7 points

Participant type(s)
Healthy volunteer, Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Cognitive or neurological deficits
2. Inability to complete questionnaires

3. Severe alcoholism
4. Presence of craniofacial malformations
5. Active neoplastic disease
6. History of orofacial muscle rehabilitation or prior OSA treatment (surgery, MAD, CPAP)

Date of first enrolment
05/05/2025

Date of final enrolment
05/12/2025

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Quironsalud Marbella
Avda Severo Ochoa 22
Marbella
Spain
29603

Study participating centre
Hospital Quironsalud Palmones
Edificio Arttysur. Avda de los Empresarions s/n Parque Empresarial las Marisma de Palmones
Palmones
Spain
11379

Sponsor information

Organisation
Hospital Quirosalud Marbella

Sponsor details
avda severo ochoa 22
Marbella
Spain
29603
+34 952774200
fgonzasan@gmail.com

Sponsor type
Hospital/treatment centre

Website
https://www.quironsalud.com/marbella

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned pulication in a peer-reviewed journal.

Intention to publish date
05/01/2026

Individual participant data (IPD) sharing plan
The dataset generated during and/or analysed during the current study will be available upon request from Dr Eduardo Correa educorreaorl@gmail.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			06/05/2025	No	Yes
Protocol file			06/05/2025	No	No