

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

Submission date 04/05/2025	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 06/05/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 07/04/2026	Condition category Ear, Nose and Throat	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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 August 2026

Who is funding the study?
Investigator initiated and funded

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

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

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Additional identifiers

Protocol serial number

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

Study type(s)

Prevention, Quality of life, Screening

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(s)

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

Key secondary outcome(s)

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)

Completion date

01/08/2026

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

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

75 years

Sex

All

Total final enrolment

0

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

01/08/2026

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 Empresarios s/n Parque Empresarial las Marisma de Palmones
Palmones
Spain
11379

Sponsor information

Organisation
Hospital Quirosalud Marbella

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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