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

Submission date
04/05/2025

Recruitment status
No longer recruiting

Registration date
06/05/2025

Overall study status
Completed

Last Edited
12/08/2026

Condition category
Ear, Nose and Throat

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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 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@quironsalud.es

Contact information

Type(s)
Public, Scientific, Principal investigator

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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

Primary study design
Observational

Study design
Prospective controlled quasi-experimental pilot study

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)

Added 07/07/2026:
Exploratory outcomes:
1. Presence and classification of the Palatal-Tongue Clinical Sign (PTCS sign) assessed during standardized oral clinical examination at baseline and after 3 months
2. Maxillary intermolar distance (palatal width) measured in millimetres using a digital caliper (vernier caliper) during the baseline clinical assessment

Completion date
01/08/2026

Eligibility

Key inclusion criteria
Current inclusion criteria as of 07/07/2026:
Cases:
1. Age between 18 and 75 years
2. Diagnosis of severe obstructive sleep apnea (AHI >30 events/hour) 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

Previous 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
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
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 Empresarions 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?
Results article		29/09/2025	12/08/2026	Yes	No
Participant information sheet			06/05/2025	No	Yes
Protocol file			06/05/2025	No	No