ISRCTN12596010 https://doi.org/10.1186/ISRCTN12596010

Evaluation of muscle activity patterns in patients with severe obstructive sleep apnea

Submission date
20/03/2021

Recruitment status
No longer recruiting

Registration date
24/03/2021

Overall study status
Completed

Last Edited
27/02/2023

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Obstructive Sleep Apnoea/Hypopnoea Syndrome (OSAHS) is a condition whereby the upper airways collapse intermittently and repeatedly during sleep. This can vary between an apnoea (no airflow through the airways) and a hypopnoea (a reduction of airflow through the airways). Deciding the best course of treatment for OSAHS can be difficult without knowing which muscles are not working correctly. A relatively new technique for visually assessing the muscles is called the OMES protocol (Orofacial Myofunctional Evaluation Protocol with Scores).
The aim of this study is to compare the OMES protocol with other available measures of tongue muscle strength.

Who can participate?
Patients diagnosed with sleep apnoea-hypopnoea at the participating hospitals

What does the study involve?
Selection visit: an initial sleep study (with measurement of baseline AHI, night-time oxygen desaturation index and the lowest night-time oxygen saturation figures)
One-off visit: The patient is evaluated by the speech therapist and fills in the sleepiness questionnaires, following which the OMES protocol is applied and the evaluation is carried out with the IOPI (Iowa Oral Performance Instrument) and the digital spoon.

What are the possible benefits and risks of participating?
None

Where is the study run from?
Hospital Quironsalud Marbella (Spain)

When is the study starting and how long is it expected to run for?
March 2021 to September 2022

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Carlos O'Connor Reina, coconnor@us.es.

Contact information

Type(s)
Scientific

Contact name
Dr Carlos O'Connor Reina

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

Contact details
Avda Menendez y Pelayo 44 5c
Sevilla
Spain
41003
+34 952774200
carlos.oconnor@quironsalud.es

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
AWGAP-2021-02

Study information

Scientific Title
Validation of Orofacial Myofunctional Evaluation Protocol with Scores (OMES) with objective measurement of oropharyngeal muscle tone using Iowa Oral Performance Instrument (IOPI) and tongue digital spoon in severe obstructive sleep apnea hypopnea syndrome (OSAHS)

Acronym
OMESIOPITDS

Study objectives
The use of the OMES protocol can be complemented by the values obtained through the IOPI instruments and the tongue digital spoon in severe OSAHS patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/03/2021, The Research Ethics Committee of the Hospital Provincial de Málaga (Regional University Hospital, 7th floor Pabellón A, Avda. –Carlos Haya s / n. 29010-Malaga, Spain; +34 951 29 1447; no email address available), ref: AWGAP-2021-02

Study design
Prospective controlled quasi-experimental pilot study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Sleep apnoea, severe obstructive sleep apnea-hypopnea syndrome

Interventions
A myofunctional evaluation of the patient diagnosed with OSAHS will be conducted in the same week as the polysomnography is performed. During this evaluation, patients are blindly examined by a speech therapist and their examination is recorded on video for later evaluation.

The patient will sit one metre away from the camera with their feet flat on the floor and their back supported by the backrest. The camera (Sony CCD-TRV138 Handycam camcorder: Sony Electronics, San Diego, CA 92127, USA) will be placed on a tripod at face and shoulder height. The evaluation with the OMES protocol (Annex 4) will then take place, based on the analysis of the following parameters:
1. Appearance/posture
2. Mobility
3. Functions
3.1. Respiration
3.2. Deglutition
3.3. Mastication

As a result of this evaluation with the already validated protocol, the higher the score, the more normal the patient's stomatognathic system.
Subsequently, the muscle tone of the genioglossus muscle and the buccinator muscle are evaluated, taking three measurements of each one and using the highest value.

Finally, the tone of the tongue muscles is measured with the digital spoon, taking three measurements and using the highest one.
The recordings and the data obtained will also be blindly analysed by another examiner.

Intervention Type
Other

Primary outcome(s)
Function of the stomatognathic musculature of patients measured a single time point using:
1. The OMES protocol (visual inspection)

2. The digital spoon to measure tongue pressure
3. The IOPI (Iowa Oral Performance Instrument) to measure tongue strength and resistance with the genioglossus and buccinator muscle tone

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
18/09/2022

Eligibility

Key inclusion criteria
Current inclusion criteria as of 29/03/2021:
Cases:
1. Ages between 18 and 75 years
2. Diagnosis of moderate to severe OSAHS (AHI>30) without having had previous experience of said condition and not undergoing treatment due to different circumstances
3. Not having undergone any previous treatment for OSAHS
4. Signed informed consent (IC) form

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

Previous inclusion criteria:
Cases:
1. Ages between 18 and 75 years
2. Diagnosis of moderate to severe OSAHS (AHI>15) without having had previous experience of said condition and not undergoing treatment due to different circumstances
3. Not having undergone any previous treatment for OSAHS
4. Signed informed consent (IC) form

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

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Sex
All

Total final enrolment
49

Key exclusion criteria
1. Cognitive or neurological deficit
2. Inability to answer questionnaires
3. Severe alcoholism
4. Presence of craniofacial malformations
5. Active neoplastic disease
6. History of prior orofacial muscle rehabilitation therapy and any prior apnoea treatment which may modify the study results (surgery, MAD, CPAP)

Date of first enrolment
07/04/2021

Date of final enrolment
17/09/2022

Locations

Countries of recruitment
Spain

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

Study participating centre
Hospital Quironsalud Campo de Gibraltar
Edificio Arttysur. Av de los Empresarios s/n
Palmones Cadiz
Spain
11379

Sponsor information

Organisation
Hospital Qironsalud Marbella

Funder(s)

Funder type
Other

Funder Name
investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		07/02/2023	27/02/2023	Yes	No
Protocol article		01/06/2021	14/06/2021	Yes	No
Participant information sheet			24/03/2021	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			24/03/2021	No	No