

How muscle exercise affects the amount of fat in the tongue of patients with obstructive sleep apnea, using ultrasound to measure the changes

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Registration date 09/03/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 28/01/2025	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Sleep apnea is a sleep disorder characterized by breathing interruptions during sleep. It occurs when the muscles in the back of the throat fail to keep the airway open, causing a person to stop breathing for a brief period of time. These interruptions can last from a few seconds to a few minutes and may occur many times during the night. Obstructive sleep apnea is the most common type and occurs when the muscles in the back of the throat relax and block the airway. Myofunctional therapy is a type of exercise therapy that aims to improve the function of the muscles in the face, mouth, and throat. It involves exercises that are designed to improve breathing, swallowing, and speech, and can be used to treat a range of conditions such as sleep apnea, speech disorders, and TMJ disorders. The therapy may involve exercises that target the tongue, lips, cheeks, and jaw muscles, as well as breathing exercises and postural adjustments. This study examines how myofunctional therapy affects the amount of fat in the tongue of patients with obstructive sleep apnea, using ultrasound to measure the changes.

Who can participate?

Patients aged 18 - 75 years with obstructive sleep apnea.

What does the study involve?

Participants will be randomly allocated to one of three groups:

Control group. Patients with recent moderate-severe sleep apnea (1-3 months) undergoing treatment with positive pressure therapy (CPAP). An initial ultrasound measurement of tongue genioglossus fat will be made and 3 months after inclusion in the study.

MT group - moderate apnea. Only and exclusively MT exercises once a day for 3 months through the AirwayGym application. An initial ultrasound measurement and DISE will be made with control at 3 months.

MT-CPAP severe apnea group. They will use CPAP at night, measuring the number of hours they use it at night. A new sleep study will be performed at 3 months. An initial ultrasound measurement and DISE will be made with control at 3 months.

What are the possible benefits and risks of participating?

The potential benefits are to improve his sleep apnea disease in order to demonstrate another therapy goal to be treated as is the tongue fat measured by ultrasound.

There will be no risks for no participation as all the patients are receiving recognized treatment.

Where is the study run from?

Hospital Quiron Salud Marbella (Spain)

When is the study starting and how long is it expected to run for?

October 2022 to September 2025

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)

Principal investigator

Contact name

Dr Carlos O'Connor-Reina

ORCID ID

<https://orcid.org/0000-0002-1670-4235>

Contact details

Avda Severo Ochoa 22

Marbella

Spain

29603

+34 952780540

carlos.oconnor@quironosalud.es

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

AWGAP-20232

Study information

Scientific Title

Influence of oropharyngeal exercises in genioglossus fat measured by ultrasound in sleep apnea patients

Acronym

TONGUEFATULTRASOUNDMT

Study objectives

Neck ultrasound is useful to better assess the response to MT treatment than tools that only measure muscle strength.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 23/02/2023, Malaga Comite de Ética de la Investigación Provincial de Malaga (Hospital Universitario Regional de Málaga Carlos Haya, Malaga, Spain; +34951 291 977; eticainvestiga.hch.sspa@juntadeandalucia.es), ref: AWAGP-20232

Study design

Multicenter randomized quasi-experimental controlled prospective pilot study

Primary study design

Interventional

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Sleep apnea

Interventions

Participants are randomised into groups using an online tool.

1. Control group. Patients with recent moderate-severe sleep apnea (1-3 months) undergoing treatment with positive pressure therapy (CPAP). An initial ultrasound measurement of tongue genioglossus fat will be made and 3 months after inclusion in the study.
2. MT group - moderate apnea. Only and exclusively MT exercises once a day for 3 months through the AirwayGym application. An initial ultrasound measurement and DISE will be made with control at 3 months.
3. MT-CPAP severe apnea group. They will use CPAP at night, measuring the number of hours they use it at night. A new sleep study will be performed at 3 months. An initial ultrasound measurement and DISE will be made with control at 3 months.

DISTRIBUTION OF VISITS TO THE CENTER:

The visits during the study are distributed as follows:

SELECTION VISIT: In patients diagnosed with OSA in a pulmonology laboratory through an initial sleep study (with baseline AHI measurement, nocturnal desaturation index, and the lowest O₂ saturation figures during the night), the inclusion and exclusion criteria obtained through the sleep study, they are informed about the study and after reading and resolving their doubts, the patient accepts and signs the IC in duplicate, taking a copy home.

ENT VISIT: The patient is assessed by the otolaryngologist and if he meets the anatomical inclusion criteria, he becomes part of one of the study groups for initial DISE and lingual force measurements with IOPI and digital spoon.

ULTRASOUND VISIT. A neck ultrasound will be performed, which will include the measurements of the ultrasound intensity, width and height of the tongue measured in initial mm prior to the initial DISE.

MONTHLY CONTROL BY TELEMEDICINE. During the 3 months of the study, each patient in the 3 groups will be monitored for adherence and incidents to the prescribed treatment.

CONTROL 3 MONTHS. A measurement of all the variables evaluated at the initial visit will be repeated.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Tongue fat measured in millimeters by ultrasound pre and post-oropharyngeal exercises (baseline and 3 months)

Key secondary outcome(s)

Measured pre and post-oropharyngeal exercises (baseline and 3 months):

1. Drug induced sleep endoscopy findings measured using VOTE classification
2. Apnea hypopnea index (apneas per hour measured) using polysomnography
3. Minimal oxygen desaturation measured using polysomnography
4. Oxygen index desaturation measured using polysomnography
5. Tongue force and buccinator muscle, IOPI scores measured in kilopascals using IOPI Iowa oral performance instrument
6. Tongue force using digital spoon measured in g/cm^2
7. Sleepiness measured using Epworth sleepiness questionnaire
8. BMI Body mass index m/kg^2
9. Neck circumference cm
10. Waist circumference cm

Completion date

01/09/2025

Eligibility

Key inclusion criteria

1. Aged between 18-75 years.
2. Diagnosis of moderate-severe OSA ($\text{iah} > 15$).
3. Not having used any previous treatment other than that of the study or lasting longer than 3 months in the case of the control group.
4. Signature of informed consent (IC).
5. Present good permeability and nasal function.
6. $\text{BMI} < 30 \text{ kg}/\text{m}^2$.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

75 years

Sex

All

Key exclusion criteria

1. Cognitive or neurological deficit.
2. Inability to complete questionnaires.
3. Severe alcoholism.
4. Presence of craniofacial malformations.
5. Active neoplastic disease.
6. History of previous rehabilitation treatment of the orofacial musculature as well as any other treatment for previous apnea that could modify the results of the study (Surgery, MAD).
7. Temporomandibular joint dysfunction
8. Ankyloglossia of the tongue or inability to perform MT exercises.
9. Not having a smartphone or inability to manipulate it, or internet network at home.
10. BMI >30 kg/m²
11. Weight changes with an increase of more than 5kg during the 3 months of study.

Date of first enrolment

30/04/2023

Date of final enrolment

01/05/2025

Locations

Countries of recruitment

Spain

Study participating centre

Hospital Quiron Salud 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

Spain
11379

Sponsor information

Organisation

Hospital Quironsalud 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 are/will be available upon request from (Dr Carlos O'Connor-Reina carlos.oconnor@quironsalud.es

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		30/01/2024	15/05/2024	Yes	No
Participant information sheet			09/03/2023	No	Yes