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

Submission date
04/03/2023

Recruitment status
No longer recruiting

Registration date
09/03/2023

Overall study status
Ongoing

Last Edited
28/01/2025

Condition category
Nervous System Diseases

[X] 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
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 postive 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@quironsalud.es

Contact information

Type(s)
Principal Investigator

Contact name
Dr Carlos O´Connor-Reina

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

Contact details
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-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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
See additional files

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 postive 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 02 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.
ULTRSOUND 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 measure
Tongue fat measured in millimeters by ultrasound pre and post-oropharyngeal exercises (baseline and 3 months)

Secondary outcome measures
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 grm/cm²
7. Sleepiness measured using Epworth sleepiness questionnaire
8. BMI Body mass index m/kg²
9. Neck circunference cm
10. Waist circumference cm

Overall study start date
30/10/2022

Completion date
01/09/2025

Eligibility

Key inclusion criteria
1. Aged between 18-75 years.
2. Diagnosis of moderate-severe OSA (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. BMI < 30 kg/m².

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
45

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

Sponsor details
Avda Severo Ochoa 22
Marbella
Spain
29603
+34 952774200
investigacion.mlg@quironsalud.es

Sponsor type
Hospital/treatment centre

Website
https://www.quironsalud.es

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer reviewed journal. After the analysis of the results obtained, the results will be disseminated by sending Communications to regional, national and international congresses of otorhinolaryngology, sleep and pulmonology. Manuscripts will be written to be sent to national and international scientific journals in the field of otorhinolaryngology and pulmonology.

Intention to publish date
23/06/2025

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?
Participant information sheet			09/03/2023	No	Yes
Protocol article		30/01/2024	15/05/2024	Yes	No