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Can treating ankyloglossia (tongue-tie) cure sleep apnea (breathing difficulty during sleep)?

Submission date
30/06/2024

Recruitment status
Recruiting

Registration date
04/07/2024

Overall study status
Ongoing

Last Edited
04/07/2024

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Obstructive sleep apnea (OSA) is a breathing disorder during sleep characterized by repeated airway blockages, often due to various factors. It is common in the population and can lead to cardiovascular issues. Treatment usually involves the use of a device called continuous positive airway pressure (CPAP).

To understand OSA, we need to consider its diverse causes, which require personalized treatment. Anatomical factors contributing to OSA include issues like nasal septum deviation, enlarged tonsils, and jaw alignment problems.

Ankyloglossia, a condition where the lingual frenulum (the tissue under the tongue) is too short, affects around 4-5% of people and can lead to difficulties in functions like sucking, chewing, and speaking. If not addressed early, it can impact breastfeeding and craniofacial development, potentially contributing to OSA later in life.

Recent studies suggest treating ankyloglossia in children can improve OSA, but evidence is lacking for adults. Our research indicates that surgical correction of ankyloglossia (frenectomy) can lead to anatomical improvements that may benefit some adults with OSA.

Diagnosis of ankyloglossia in adults follows specific protocols to assess tongue mobility and determine if surgical intervention or speech therapy is necessary.

Myofunctional Therapy (MT), a program designed for orofacial muscle disorders, has shown promise in improving upper airway muscle function and reducing OSA severity in adults. Combining MT with frenectomy may enhance outcomes by improving tongue function and nasal breathing.

Despite these findings, international sleep societies do not currently include frenulum evaluation in their guidelines for assessing OSA patients. Our research aims to demonstrate the potential benefits of ankyloglossia surgery for OSA in adults and identify factors influencing treatment success.

The main objective will be to evaluate the results of lingual frenulum surgery in patients with severe OSA.

Who can participate?
Patients diagnosed with sleep apnoea-hypopnoea and ankyloglossia

What does the study involve?
Control Group: This group consists of patients with severe obstructive sleep apnea (OSA) and ankyloglossia who choose not to have surgery. We will assess their anatomical and upper airway function. They will receive Drug-Induced Sleep Endoscopy (DISE), myofunctional therapy, and CPAP treatment.

Ankyloglossia Group: This group includes patients with ankyloglossia who show functional issues during assessment of their anatomical and upper airway function. They will undergo Drug-Induced Sleep Endoscopy (DISE), frenuloplasty surgery to correct the lingual frenulum, and myofunctional therapy.

What are the possible benefits and risks of participating?
Improving the apnea.
Risks inherent to the surgery.

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

When is the study starting and how long is it expected to run for?
May 2024 to July 2026

Who is funding the study?
Investigator initiated and funded

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

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
AWGAP-2024-1

Study information

Scientific Title
Protocol of assessment of ankyloglossia in obstructive sleep apnea. Predictive factors of surgery success and failure

Study objectives
Ankyloglossia surgery followed by myofunctional therapy in certain adult patients with OSA could reduce tongue collapse, allowing the tongue to assume its optimal position in the oral cavity and improving upper airway collapse, thereby alleviating the disorder.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 28/06/2024, CEIM Provincial de Malaga (Hospital Regional Universitario. 7ª planta Pabellón A. Avda. –Carlos Haya s/n, Malaga, 29010, Spain; +34 951 29 1447 / 951; eticainvestiga.hch.sspa@juntadeandalucia.es), ref: AWGAP-2024-1

Study design
Multicentre prospective interventional controlled non randomized

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Diagnostic, Prevention, Treatment, Efficacy

Participant information sheet
See outputs table

Health condition(s) or problem(s) studied
Prevention of obstructive sleep apnea syndrome

Interventions
Control group. Patients with severe OSA with ankyloglossia who refuse surgery. Anatomical and upper airway function assessments will be performed. They will undergo DISE myofunctional therapy and CPAP treatment.

Ankyloglossia group. Anatomical and upper airway function assessments will be performed and patients with functional alterations will undergo DISE, frenuloplasty surgery, and myofunctional therapy.

Follow up after 3 months

Intervention Type
Procedure/Surgery

Primary outcome measure
Apnea hipoapnea index (AHI) (EVENTS/HOURS) preop and after 3 months

Secondary outcome measures
1. DISE findings with vote classification preop and after 3 months in both groups
2. Functional assessment preop and after 3 months in both groups
3. Epworth questionnaires preop and after 3 months in both groups
4. Oxygen desaturation index (ODI) % preop and after 3 months in both groups
5. Iowa oral performance instrument (IOPI) kilopascals preop and after 3 months in both groups
6. Vote classification preop and after 3 months in both groups

Overall study start date
30/05/2024

Completion date
30/07/2026

Eligibility

Key inclusion criteria
Inclusion criteria: (Cases)
1. Ages between 18 and 65 years.
2. Diagnosis of moderate to severe OSA (AHI 15 to 30 adults) with no previous experience of this disorder and untreated due to different circumstances.
3. Not to have used any previous treatment for severe OSA.
4. Signing of informed consent (IC).
5. Good permeability and nasal function.
6. Patients with pathological lingual frenulum diagnosed using Marchesani protocol and confirmed by a speech therapist.
7. Friedman 1
8. Palatine Tonsil Stage Friedman 1

Inclusion criteria: (Controls)
1. Ages between 18 and 65 years.
2. Diagnosis of moderate to severe OSA (AHI15-30 adults) with no previous experience of this disorder and untreated due to different circumstances.
3. Not to have used any previous treatment for severe OSA.
4. Signing of informed consent (IC).
5. Good permeability and nasal function.
6. Patients with pathological lingual frenulum diagnosed using Marchesani protocol and confirmed by a speech therapist.
7. To have refused frenuloplasty surgery.
8. Friedman 1
9. Palatine Tonsill Stage Friedman 1

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Cognitive or neurological deficit
2. Inability to complete questionnaires
3. Severe alcoholism
4. BMI > 29 kg/m²
5. Active neoplastic disease
6. History of previous rehabilitative treatment of the orofacial musculature, as well as any previous apnoea treatment that may modify the results of the study (Surgery, MAD, CPAP)
7. Lack of smartphone access or inability to use one, or a home Internet network that prevents them from undergoing MT
8. Systemic diseases with muscle hypotonia
9. Pierre Robin Sequence or other severe craniofacial abnormalities
10. Problems with the temporomandibular joints that make it impossible to conduct MT

Date of first enrolment
15/07/2024

Date of final enrolment
15/07/2026

Locations

Countries of recruitment
Spain

Study participating centre
Ent Department.Hospital Quironsalud Marbella
Avda Severo Ochoa 22
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Study participating centre
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Study participating centre
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28023

Study participating centre
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Camino del Molino
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Study participating centre
Ent Department. Alzahra Hospital
Sheik Zayed Road
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124412

Study participating centre
ENT Department, Hospital Universitario Virgen de Valme
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Sponsor information

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Sponsor type
Hospital/treatment centre

Website
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Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
After the analysis of the results obtained, the results will be disseminated by sending communications to regional, national, and international congresses on otolaryngology, sleep, and pulmonology. Manuscripts will be written for submission to national and international scientific journals in the field of otolaryngology and pulmonology.

Intention to publish date
01/01/2027

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from the main investigator 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	in Spanish		04/07/2024	No	Yes
Participant information sheet	in Spanish		04/07/2024	No	Yes