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

Submission date	<b>Recruitment status</b> Recruiting	[X] Prospectively registered		
30/06/2024		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
04/07/2024	Ongoing	Results		
<b>Last Edited</b> 04/07/2024	<b>Condition category</b> Nervous System Diseases	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

#### Contact name

Dr Carlos O'Connor-Reina

#### **ORCID ID**

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### Additional identifiers

#### Clinical Trials Information System (CTIS)

Nil known

#### ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

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

#### Study type(s)

Diagnostic, Prevention, Treatment, Efficacy

#### 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(s)

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

#### Key secondary outcome(s))

- 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

#### 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

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Upper age limit

65 years

#### Sex

Αll

#### Key exclusion criteria

- 1. Cognitive or neurological deficit
- 2. Inability to complete questionnaires
- 3. Severe alcoholism
- 4.  $BMI > 29 \text{ kg/m}^2$
- 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 Marbella Spain 29603

#### Study participating centre Hospital Quironsalud Campo de Gibraltar

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#### Study participating centre Ent Department.Hospital Universitario Fuenlabrada

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#### Study participating centre Ent Department. Alzahra Hospital

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#### Study participating centre ENT Department, Hospital Universitario Virgen de Valme

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# 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 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes