

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

Submission date 30/06/2024	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 04/07/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 04/07/2024	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

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

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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 hypoapnea 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

All

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

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Study participating centre
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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