ISRCTN15126033 https://doi.org/10.1186/ISRCTN15126033

Ear, nose and throat structures in unilateral posterior crossbite patients before and after treatment compared to healthy control subjects

Submission date
07/07/2025

Recruitment status
No longer recruiting

Registration date
05/08/2025

Overall study status
Completed

Last Edited
05/08/2025

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Some children have a bite problem where their back teeth don't line up properly - one side sits inside the other instead of meeting correctly. This is called unilateral posterior crossbite (ULCB). When children have this problem, it might affect how they breathe, swallow, and speak. This study aims to find out if children with this bite problem have more issues with their ears, nose, and throat compared to children with normal bites. We also want to see if these problems improve after treatment with a special dental device that widens the upper jaw.

Who can participate?
Boys and girls in the early mixed dentition period (when both baby and permanent teeth are present in the mouth): a unilateral posterior crossbite (ULCB) group and a healthy control group with normal bites

What does the study involve?
Parents will answer questions about their child's breathing, snoring, allergies, and ear/nose /throat infections. An ear, nose, and throat specialist will examine the child's ears, nose, throat, and tonsils. A speech therapist will test how well the child can pronounce sounds. A dental specialist will check how the child breathes, swallows, and whether their lips close properly. The child's teeth and bite will be examined and scanned.
Children in the ULCB group will receive treatment with a special device called a rapid maxillary expander. This device slowly widens the upper jaw over several weeks to fix the bite problem. The device stays in place for 6-9 months to keep the teeth in their new position.
All assessments will be repeated after treatment to see if there are any improvements.

What are the possible benefits and risks of participating?
Benefits:
1. Children in the ULCB group will receive treatment for their bite problem at no cost
2. All participants will receive thorough assessments of their dental, speech, and ear/nose/throat health
3. The study may help improve treatment for future children with similar problems

Risks:
1. Possible discomfort during treatment (the rapid maxillary expander may cause some discomfort when it's first fitted and during adjustments. Children might experience temporary soreness in their teeth and jaw, difficulty eating certain foods, and changes in speech for a few days)
2. Risks and discomfort associated with ENT examinations (the examinations are generally non-invasive but some children might feel nervous during the assessments. All procedures are safe and commonly used in dental practice)

Where is the study run from?
Orthos Institute (Slovenia)

When is the study starting and how long is it expected to run for?
February 2020 to October 2024

Who is funding the study?
1. Orthos Institute (Slovenia)
2. ARIS (Slovenian research and innovation agency)

Who is the main contact?
Dr Meta Grilec, grilec@orthos.si

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Aljaz Golez

ORCID ID
https://orcid.org/0000-0003-0552-1465

Contact details
Zaloska cesta 4
Ljubljana
Slovenia
1000
+386 (0)15437511
aljaz.golez@mf.uni-lj.si

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
P3-0374, project grant J3-50103

Study information

Scientific Title
Nasopharyngeal lymphoid tissue, breathing pattern and articulation disorders in children with unilateral posterior crossbite: a controlled clinical trial

Study objectives
1. The prevalence of irregularities in ear, nose and throat (ENT) structures and deviant orofacial functions is different in children with unilateral posterior crossbite (ULCB) compared to the control group.
2. The prevalence of irregularities in ENT structures and deviated orofacial functions would change before and after orthopedic treatment of ULCB.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 21/10/2024, Komisija republike Slovenije za medicinsko etiko (Slovenian Ethics Committee) (Štefanova ulica 5, Ljubljana, 1000, Slovenia; +386 (0)14786906; kme.mz@gov.si), ref: 0120-452/2024-2711-3

2. approved 15/06/2020, Interdisciplinarno strokovno posvetovalno telo Zavoda Orthos (Orthos Institute, Vilharjev podhod 18, Ljuljbana, 1000, Slovenia; +386 (0)1 519 35 40; info@orthos.si), ref: 80-81/04/06

Study design
Prospective controlled clinical study with treatment intervention

Primary study design
Interventional

Study type(s)
Diagnostic, Treatment

Health condition(s) or problem(s) studied
Unilateral posterior crossbite

Interventions
Subjects for the UPCB group, with and without deviated oral functions or poor oral habits, will be randomly selected from a pool of prepubertal patients referred for orthodontic treatment.

Prior to the clinical ENT examination, the parents or guardians of the participating children will be verbally interviewed. Information will be collected regarding daily or nocturnal breathing patterns, snoring, allergies, the occurrence of frequent sneezing or colds, the frequency and type of nasal discharge, and the occurrence of middle ear, nasal, or throat infections.

A routine clinical examination by an otolaryngologist will be performed while each child sits in a relaxed position on a chair. The ENT specialist will be blinded to the patient's orthodontic status. The ENT specialist will visually examine the eardrum (noting if it is normal or retracted), the state of the nasal mucosa (normal or oedematous), and any possible deviation of the nasal

septum. They will also assess the mobility of the tongue and perform an objective nasal breathing evaluation (determining if breathing is possible or obstructed). The size of the tonsils will be assessed using Brodsky's standardized system.

Articulation disorders will be assessed in both groups (UPCB and controls) by an experienced speech therapist (NP) at the beginning of the study. A three-position articulation test for the Slovenian language, without transcription, will be used to determine the presence or absence of an articulation disorder.

Clinical examinations will be performed by an experienced orthodontist who will document the orofacial functions and intraoral condition of the children. Each child will be observed in a relaxed position, and any cases of incompetent lip closure will be noted. If incompetent lip closure is not present, the child's breathing pattern will be recorded using a special airflow measuring device.

To assess the swallowing pattern, we will use the method proposed by Melsen et al. Each child will swallow three times, and the consensus opinion on the swallowing pattern will be accepted.

Orthodontic Assessment and Treatment (for UPCB Group):
During the intraoral examination, posterior crossbite, midline deviation, and transverse buccal relationships will be recorded in the UPCB group. The dental arches will be digitally scanned with the 3Shape TRIOS 3 scanner and analyzed with the Dolphin program. In the UPCB group, an alginate impression of the upper dental arch will be taken and cast in hard blue plaster. A rapid maxillary expander appliance (Haas type) will be fabricated in a dental laboratory (Orthos Institute, Ljubljana).

All UPCB patients will be treated according to the same clinical procedure with the same appliance: a Haas-type RME appliance with a size 8 expansion screw. Patients will be monitored weekly by the clinician during the active expansion phase. The expansion will continue until the posterior crossbite on the permanent molars is self-corrected and a transversal hypercorrection of 1.5 mm is achieved. After 6-9 months, passive fixed retention appliances (palatal arch) will be used to maintain the transversal dimension, with the expansion screw secured by a ligature wire. Patients will be monitored clinically during the follow-up period.

We expect a 4-year follow-up period.

Intervention Type
Procedure/Surgery

Primary outcome(s)
ENT structures, irregular orofacial functions and articulation disorders in children with ULCB in early mixed dentition and the healthy control group, assessed initially before the orthodontic treatment:

Main dichotomous measures (method of measurement; scale):
1. Tongue posture (orthodontic clinical evaluation; palate-mouth floor)
2. Motor function of the tongue (ENT clinical evaluation; normal-clumsy)
3. Mentalis muscle hyperactivity (orthodontic clinical evaluation; normal-hyperactive)
4. Swallowing pattern (orthodontic clinical evaluation; somatic-visceral)
5. Articulation disorders (tripositional test; test score)
6. Patient-reported presence of allergies or frequent throat infections (questionnaire; yes-no, which?)

Main ordinal measures (method of measurement; scale):
1. Eardrum condition (ENT clinical evaluation; Normal, Retracted, Exudative otitis, Acute otitis, Chronic otitis)
2. Nasal mucosa condition (ENT clinical evaluation; Normal, Swollen, Very swollen)
3. Adenoid size (ENT clinical evaluation; Small, Medium, Large)
4. Palatine tonsil size (ENT clinical evaluation; Small, Medium, Large)
5. Lip posture (ENT clinical evaluation; Closed, Pursed, Open)
6. Objective assessment of nasal breathing (ENT clinical evaluation)
7. Patient-reported snoring (questionnaire; No, Sometimes, Often)
8. Patient-reported daily (diurnal) breathing pattern (questionnaire; Nasal, Sometimes mouth, Always mouth)

Key secondary outcome(s))
ENT structures and orofacial functions in ULCB children after treatment with rapid maxillary expansion compared to baseline. The same measures will be assessed 4 years after the initial examination.

Main dichotomous measures (method of measurement; scale):
1. Tongue posture (orthodontic clinical evaluation; palate-mouth floor)
2. Motor function of the tongue (ENT clinical evaluation; normal-clumsy)
3. Mentalis muscle hyperactivity (orthodontic clinical evaluation; normal-hyperactive)
4. Swallowing pattern (orthodontic clinical evaluation; somatic-visceral)
5. Articulation disorders (tripositional test; test score)
6. Patient-reported presence of allergies or frequent throat infections (questionnaire; yes-no, which?)

Main ordinal measures (method of measurement; scale):
1. Eardrum condition (ENT clinical evaluation; Normal, Retracted, Exudative otitis, Acute otitis, Chronic otitis)
2. Nasal mucosa condition (ENT clinical evaluation; Normal, Swollen, Very swollen)
3. Adenoid size (ENT clinical evaluation; Small, Medium, Large)
4. Palatine tonsil size (ENT clinical evaluation; Small, Medium, Large)
5. Lip posture (ENT clinical evaluation; Closed, Pursed, Open)
6. Objective assessment of nasal breathing (ENT clinical evaluation)
7. Patient-reported snoring (questionnaire; No, Sometimes, Often)
8. Patient-reported daily (diurnal) breathing pattern (questionnaire; Nasal, Sometimes mouth, Always mouth)

Completion date
01/10/2024

Eligibility

Key inclusion criteria
1. Children with ULCB in the early mixed dentition period
2. Patients with all posterior teeth in crossbite (canines, primary molars and first permanent molars) that had deviated at least 2 mm unilaterally from the lower midline or had a lateral displacement of the mandible

Healthy control group:
No malocclusion

Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
5 years

Upper age limit
12 years

Sex
All

Total final enrolment
62

Key exclusion criteria
1. Orofacial syndromes
2. Orofacial cleft patients
3. Non-cooperative participants

Date of first enrolment
01/06/2020

Date of final enrolment
01/12/2021

Locations

Countries of recruitment
Slovenia

Study participating centre
Faculty of Medicine, University of Ljubljana
Vrazov trg 2
Ljubljana
Slovenia
1000

Study participating centre
Orthos Institute
Vilharjev podhod 18
Ljubljana
Slovenia
1000

Study participating centre
University Medical Centre Ljubljana
Zaloska cesta 7
Ljubljana
Slovenia
1000

Sponsor information

Organisation
Zavod Orthos

Funder(s)

Funder type
Research organisation

Funder Name
The Slovenian Research and Innovation Agency

Alternative Name(s)
Slovenian Research Agency, Javna agencija za raziskovalno dejavnost RS v angleškem jeziku: Slovenian Research Agency, Javna Agencija za Raziskovalno Dejavnost RS, The Slovenian Research and Innovation Agency (ARIS), Javna agencija za znanstvenoraziskovalno in inovacijsko dejavnost Republike Slovenije, ARRS, ARIS

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Slovenia

Funder Name
Orthos Institute (Slovenia)

Results and Publications

Individual participant data (IPD) sharing plan
Data will be incorporated into the article. Some of the data contains sensitive personal information and is therefore protected by national and EU laws (GDPR). However, data that does not jeopardise the privacy of study participants may be made available by the corresponding author (AG or MG) upon reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan			08/07/2025	No	No