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Evaluation of oxygen and serum levels of growth hormone and bone growth after orthodontic treatment in growing patients

Submission date 11/05/2023	**Recruitment status** Recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 31/05/2023	**Overall study status** Ongoing	
Last Edited 14/02/2025	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
There are two treatment options for children with a crossbite in the back teeth. The first treatment includes the placement of an expansion appliance that attaches to the upper back teeth followed by having the child wear braces. The second option includes following the child until their permanent (adult) teeth come and then treating the crossbite with the expansion appliance and braces at that point. This study aims to determine if the expansion of the upper jaw using the expansion appliance before the adult teeth come in will increase levels of growth hormone in the body and improve the growth and development of children in general. This may happen because the expansion device changes the upper jaw that is attached to the nose and thus increases the nasal area for air intake. As such, the purpose of this study was to try to see if there may be a benefit to treating a crossbite before the adult teeth come in.

Who can participate?
Children aged between 7 and 10 years old who have irregularity in the width of the upper jaw

What does the study involve?
The study tests this by measuring levels of growth hormones in the blood. The stud team also want to verify if the breathing pattern is affected when expanding the upper jaw. This is measured by having children in the study do a sleep breathing test, where their breathing patterns and oxygen levels are measured while they sleep.

What are the possible benefits and risks of participating?
This study may benefit a child because there is evidence to suggest that the amount of air intake affects the amount of growth hormone in the body.

Where is the study run from?
Faculty of Medicine and Dentistry, University of Alberta (Canada)

When is the study starting and how long is it expected to run for?
January 2016 to December 2026

Who is funding the study?
Faculty of Medicine and Dentistry, University of Alberta (Canada)

Who is the main contact?
Prof. Manuel Lagravere (PI), manuel@ualberta.ca (Canada)

Contact information

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Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Pro

Study information

Scientific Title
Evaluation of oxygen saturation and serum levels of growth hormone and bone growth mediators after rapid maxillary expansion in growing patients

Study objectives
The evidence of metabolic and/or hormonal changes in patients after rapid maxillary expansion (RME) due to changes in the breathing pattern might open new points of view for diagnosis and treatment planning. This change in breathing pattern would be extrapolated by observing a reduction in apnoea/hypopnoea index (AHI) and an increase in oxygen saturation suggesting a shift from prevalent oral breathing to nasal breathing. This premise is based on that nasal breathing allows for greater oxygenation of the blood since it is more physiological than oral breathing. Moreover, a decrease in AHI suggests that nasal breathing is at least partially restored. By selecting the ones that improved and analyzing the metabolic effects changes in GH and other mediators in those cases it might improve our understanding of the systemic effects of maxillary expansion in growing individuals.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/03/2016, University of Alberta, Health Research Ethics Board - Biomedical Panel (Research Ethics Office, 2-01 North Power Plant (NPP), Edmonton, Alberta T6N 2N2, Canada; +1 780 492 0459; reoffice@ualberta.ca), ref: Pro00061538

Study design
Randomized controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Dental clinic, Home, Laboratory

Study type(s)
Screening, Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Posterior crossbite

Interventions

The changes in growth hormone (GH) levels that the patients will show at the two timepoints will be first compared to a control group of the same age and this will allow the evaluation of significant cut-off levels. Moreover, GH levels at T1 and T2 will be compared to normal GH values at the same age and will be considered significant if higher than 2 standard deviations from normal increases for age and sex.

The whole sample was divided into a treatment group and a control group according to a randomization list. Children in the control group will receive RME treatment after the end of the study interval time. Postponing treatment for the control group will not change the efficacy of treatment in this group since RME might be easily performed until mid palatal suture maturation at the pubertal growth spurt, which is a long way for the control group.

Exclusion of patients in the pubertal growth spurt. Spontaneous growth hormone secretion increases during puberty in normal girls and boys. It has been shown that GH levels increase significantly during pubertal growth spurt. According to previous results the increase in mean levels was earlier in girls than boys, was most evident at night, and was due to increased pulse amplitude rather than a change in pulse frequency.

Polysomnography (PSG) will consist of a take-home device which patients will use the first day and return to the doctor the following day. The data collected by the device will be analyzed by a specialized pediatrician. Blood samples will be collected and results will also be interpreted by a specialized pediatrician. In this interval, treatment group subjects will undergo RME and the control group will undergo no treatment. PSG exam will allow the exclusion of obstructive sleep apnea patients.

Cone-beam computer tomographies (CBCT) will be obtained using the I-Cat New Generation (Imaging Science International, Hatfield, PA, USA). The image-taking protocol will use a large field of view 9in x 12in, 4 seconds, voxel size 0.30mm, 120 kVp, 23.87 mAS. Raw images will be exported into a DICOM file, which will be subsequently loaded into AVIZO software (version 8.1, Visualization Sciences Group, Burlington, MA, USA) for analysis. CBCTs will be taken at T0 and T1 being 12 months apart.

Skeletal expansion before and after rapid maxillary expansion (RME) (12 months period) will be evaluated by plaster models and analyzing CBCT images. In order to determine reliability, ten random datasets will be measured by the principal investigator 3 times (with one-week intervals between measurements). Inter-reliability will be obtained by having three other investigators measure the datasets twice (one month between measurement trials).

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Upper jaw expansion orthodontic treatment

Primary outcome measure

Effects of rapid maxillary expansion on breathing measured by analyzing CBCTs, photos, airway measures and questionnaires at T0, T12 months and T End

Secondary outcome measures
Blood measurement of Serum bone alkaline phosphatase, calcium, phosphorus and Vitamin D levels using standard laboratory procedures at T0, T12 months and T End

Overall study start date
15/01/2016

Completion date
24/12/2026

Eligibility

Key inclusion criteria
1. Good general health according to medical history and clinical examination
2. Maxillary transverse discrepancy (skeletal discrepancy) with or without unilateral posterior crossbite
3. Age between 7 and 10 years old (this age range was chosen to prevent bias in terms of pubertal peak growth since at this age it is assumed males and females have not had it yet)
4. Body mass index (BMI) is healthy (not below the 25th percentile and not above the 75th percentile) according to age.

Participant type(s)
Healthy volunteer, Patient

Age group
Child

Lower age limit
7 Years

Upper age limit
10 Years

Sex
Both

Target number of participants
120

Total final enrolment
120

Key exclusion criteria
Patients in the pubertal growth spurt

Date of first enrolment
18/11/2016

Date of final enrolment
20/07/2026

Locations

Countries of recruitment
Canada

Italy

Study participating centre
Kaye Edmonton Clinic, University of Alberta
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Study participating centre
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Sponsor type
University/education

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Funder(s)

Funder type
University/education

Funder Name
Faculty of Medicine and Dentistry, University of Alberta

Alternative Name(s)
Faculty of Medicine & Dentistry - University of Alberta, University of Alberta Faculty of Medicine and Dentistry, Faculty of Medicine and Dentistry at University of Alberta, University of Alberta Faculty of Medicine & Dentistry, Faculty of Medicine & Dentistry - University of Alberta, University of Alberta Faculty of Medicine and Dentistry, FoMD

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Canada

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal
Shared in national and international conferences

Intention to publish date
30/10/2025

Individual participant data (IPD) sharing plan
The dataset generated during and analyzed during the current study will be stored in a non-publicly available repository at University of Alberta. The type of data stored are blood measurement of serum bone alkaline phosphatase, calcium, phosphorus and Vitamin D. The process for requesting access is through Ethics Committee and custodian approvals. These data will be available at the end of the study. Consent from participants was required and obtained. Data will be stored with patients charts numbers.

IPD sharing plan summary
Stored in non-publicly available repository