

Airway obstruction in children with congenital hypoplasia of the mandible.

Published: 27-03-2012

Last updated: 15-05-2024

Primary objectives:1a. To determine the severity and course of obstructive sleep apnea in children with congenital mandibular hypoplasia (both isolated and syndromal).1b. To determine the growth pattern of the lower face in relation to the upper...

Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON37826

Source

ToetsingOnline

Brief title

Relation mandibular hypoplasia and airway obstruction

Condition

- Other condition

Synonym

retrognathia, small lower jaw

Health condition

Craniofaciale aandoeningen

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Mandibular hypoplasia, Upper Airway Obstruction

Outcome measures

Primary outcome

Outcomes of physical examination:

- length in centimetres
- head circumference in millimetres
- weight in kilograms

Outcomes of polysomnography:

- Apnea Hypopnea Index (AHI)
- Oxygen Desaturation Index (ODI)

Outcomes of ENT exam and nasoendoscopy:

- Malampatti score
- Cormack-Lehane score
- Sher-classification

Outcomes of measurements on :

- distances in millimetres

Secondary outcome

Study description

Background summary

A common problem in children with a craniofacial anomaly is an upper airway obstruction. This obstruction may be seen at the level of the lower face and/or the level of the midface. Early recognition of symptoms and prompt effective treatment by a specialised craniofacial team are important aspects for successful care in these children. This study will focus on airway obstruction at the level of the lower face in children with congenital mandibular hypoplasia (both isolated and syndromal).

Study objective

Primary objectives:

- 1a. To determine the severity and course of obstructive sleep apnea in children with congenital mandibular hypoplasia (both isolated and syndromal).
- 1b. To determine the growth pattern of the lower face in relation to the upper airway in children with congenital mandibular hypoplasia.

Secondary objectives;

- 2a. To evaluate prevalence, characteristics and management of feeding difficulties.
- 2b. To assess the long-term outcome and complications of mandibular distraction surgery.
- 2c. To assess the reliability and validity of ultrasonographic imaging for cephalometric measurements on the mandible.

Study design

Observational study, both prospective cohort study and cross-sectional.

Study burden and risks

Disadvantages of participation in this study are the extra time necessary for the study visit(s), the extra time necessary to fill out the questionnaires and the small risk for adverse events. the nasoendoscopy could be related to adverse events. the lateral and posterior-anterior-X-ray both give radiation exposure (0.005 mSv). This is about the same amount of background radiation we are exposed in our daily life (0.0065 mSv). Serious adverse events related to the study are not expected. All unexpected adverse events reported spontaneously by the patient or observed by the investigator or her staff will

be recorded and reported to the appropriate authority.

Contacts

Public

Erasmus MC, Universitair Medisch Centrum Rotterdam

's-Gravendijkwal

3015CE

NL

Scientific

Erasmus MC, Universitair Medisch Centrum Rotterdam

's-Gravendijkwal

3015CE

NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Children (2-11 years)

Inclusion criteria

Study Population 1a:

- Age between 0 and 3 months

- Presence of a congenital mandibular hypoplasia; Study Population 1b:

- age between 3 months and 18 years old

- Presence of congenital mandibular hypoplasia; Study population 2:

- Below the age of 18 years old

- 3D CT-scan of the head as part of regular patient care; Control Population 1a:

- Age below 3 months

- Presence of cleft palate
- No congenital mandibular hypoplasia;Control population 1b:
- Age between 3 months and 18 years old
- Presence of cleft palate;Control Population 2:
- Age below 3 months
- Presence of an immature breathing pattern, but otherwise healthy

Exclusion criteria

Control population 2:

- Congenital malformation
- Underlying condition that is known to influence growth

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL	
Recruitment status:	Will not start
Enrollment:	525
Type:	Anticipated

Ethics review

Not approved	
Date:	27-03-2012
Application type:	First submission

Review commission:

METC Erasmus MC, Universitair Medisch Centrum Rotterdam
(Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 26550

Source: NTR

Title:

In other registers

Register	ID
CCMO	NL37895.078.12
OMON	NL-OMON26550