Airway obstruction in children with congenital mandibular hypoplasia.

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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	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON37722

Source
ToetsingOnline

Brief title
Relation mandibular hypoplasia and airway obstruction.

Condition

- Other condition

Synonym
small lower jaw, underdevelopment of the lower jaw

Health condition

Craniofaciale afwijkingen

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,Fonds Nuts Ohra

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 CT-scans:

- Distances in millimetres.

Secondary outcome

N/A.

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 succesful 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.

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 invasive 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
- Psychological burden of the stay at the ICU (in study population Ia and control population Ia)
- The small risk for adverse events
(- Nasoendoscopy will only be done during palatal closure (under anaesthesia).

Serious adverse events related to the study are not expected.
All unexpected (serious) adverse events reported by the patient or observed by the investigator or her staff will be recorded and reported to the appropriate authority and to the staff.

The benefit of this project is the early recognition of an obstructive sleep apnea (OSA) syndrome and its early treatment, thereby possibly preventing negative long-term effects of OSA. Furthermore feeding and growth will be closely monitored giving the opportunity for early intervention if necessary.

The main aim of the study is to establish the relation between airway obstruction and mandibular hypoplasia, and to measure mandibular growth. Mandibular hypoplasia is a congenital condition and can cause airway obstruction which often manifests in the neonatal period. It is therefore necessary to study this condition and its associated morbidity from an early age in this specific group. Because growth of the mandible can influence the airway obstruction we should investigate this at an early age as well.

Contacts

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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
- 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
- Without congenital mandibular hypoplasia;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 not 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:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-10-2012
Enrollment:	313
Type:	Actual

Ethics review

Approved WMO

Date:	30-08-2012
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

No registrations found.

In other registers

Register	ID
CCMO	NL40418.078.12