Airway obstruction in children with congenital hypoplasia of the mandible.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26550

Source
NTR

Brief title
CMH

Health condition

Congenital mandibular hypoplasia

Sponsors and support

Primary sponsor: Erasmus University Medical Center
Source(s) of monetary or material Support: Erasmus University Medical Center

Intervention

Outcome measures

Primary outcome

Outcomes of physical examination:

1. Length in centimetres;

2. Head circumference in millimetres;

3. Weight in kilograms.

Outcomes of polysomnography:

1. Apnea Hypopnea Index (AHI);

2. Oxygen Desaturation Index (ODI).

Outcomes of ENT exam and nasoendoscopy:

1. Malampatti score;

2. Cormack-Lehane score;

3. Sher-classification.

Outcomes of measurements on:

1. Distances in millimetres.

Secondary outcome

N/A

Study description

Background summary

The aim of this study is to establish the relation between congenital mandibular hypoplasia and upper airway obstruction using a prospective cohort and cross-sectional study design. Furthermore, we aim to analyse the craniofacial growth pattern, feeding problems and mandibular distraction outcome in children with congenital mandibular hypoplasia. Also we will determine the reliablity of ultrasonography compared to 3D-CT scans in measurement of the mandible.

Study objective

Children with congenital mandibular hypoplasia are at risk for development of airway

obstruction.

Study design

Exams in both study population 1a / control population 1 b / control population 2 will take place at the age of 3 months, 6 months, 9 months, 1 year, 2 years, 3 years, 4 years and 6 years old.

Exams in study population 1b / control population 1b are cross-sectional and will consist of one study visit.

Exams in study population 2 are cross-sectional and will take place directly after the 3D-CT scan.

Intervention

This will be an invasive observational study in which patients in both study population 1a and control population 1a / 2 will undergo a number of exams and tests to address objectives 1a / 1b / 2a / 2b. The test and exams are:

1. Polysomnography (for the detecting of OSA, two clinical PSG's in the first year, and thereafter an ambulant PSG once a year);

2. Endoscopy (to assess the type and severity of airway obstruction, in the first year);

3. Lateral skull X-ray (to assess the skull morphometrics, when the child is > 6 year on an annual basis);

4. Ultrasonography (to assess mandibular growth, annually);

5. Jaw-index (to assess mandibular growth, annually);

6. OSA-18/OSA-12 (to assess presence of OSA and QOL, annually).

For the reliabity and validity study of ultrasonography all children in study population 2 (who undergo a 3D-CT scan as part of regular patient care) will get an ultrasound exam of the mandible.

Contacts

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Eligibility criteria

Inclusion criteria

Study Population 1a:

1. Age between 0 and 3 months;

2. Presence of a congenital mandibular hypoplasia.

Study Population 1b:

1. Age between 3 months and 18 years old;

2. Presence of congenita mandibular hypoplasia.

Study population 2:

1. Below the age of 18 years old;

2. 3D CT-scan of the head as part of regular patient care.

Control Population 1a:

1. Age below 3 months;

2. Presence of cleft palate;

3. No congenital mandibular hypoplasia.

Control population 1b:

1. Age between 3 months and 18 years old;

2. Presence of cleft palate.

Control Population 2:

1. Age below 3 months;

2. Presence of an immature breathing pattern, but otherwise healthy.

Exclusion criteria

N/A

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-10-2012
Enrollment:	525
Type:	Anticipated

Ethics review

Positive opinion

Date:	10-02-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 37826
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3163
NTR-old	NTR3307
CCMO	NL37895.078.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON37826

Study results

Summary results
N/A