Three-dimensional photographic imaging of children with orofacial clefts; A longitudinal cohort study into 3D facial growth of children with non-syndromic orofacial clefts (OFC)

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON30900

Source
ToetsingOnline

Brief title
3D facial growth in children with orofacial clefts

Condition

- Other condition

Synonym
cleft palate

Health condition

schisis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Children, Cleft palate, Facial growth, Imaging, three-dimensional

Outcome measures

Primary outcome

Differences in soft tissue facial growth between case and control group will be

evaluated by measurement of three-dimensional facial volume changes and changes

in landmark position over time during the first 6 years of life.

Secondary outcome

Not applicable

Study description

Background summary

Medical imaging has moved from two-dimensional representations to more sophisticated 3D techniques. Nowadays it is possible to study facial morphology in patients with orofacial clefts three-dimensionally. This longitudinal study will describe the three-dimensional facial growth of cleft patients compared to controls using the stereophotogrammetry method. Stereophotogrammetry is a non-invasive method without any form of radiation.

Study objective

The aim of this longitudinal prospective study is to investigate facial morphology in children with and without orofacial clefts three-dimensionally using noninvasive stereophotogrammetry in order:
- to establish reference values for normal facial growth and development
- to evaluate facial growth and treatment outcome in children with orofacial

clefts

Study design

Observational study; longitudinal cohort study

No intervention

Study burden and risks

Children with OFC are photographed 13 times in the first 6 years of life as much as possible during the regular visits at the Cleft Palate Craniofacial Unit. These photographs are taken by means of the non-invasive 3D stereophotogrammetry method without exposure to ionizing radiation. During each visit a short questionnaire about the history of the child's health will be taken from the parents and the child's weight, length, head circumference, relative sitting height and arm span are measured.
The control group of healthy newborns and their parents have to come to the Radboud University, Medical Centre 13 times during the first 6 years of their child's life. A 3D picture will be taken and a short questionnaire. The child's weight, length, head circumference, relative sitting height and arm span are measured as well. The study can only be done using this control group, because three-dimensional reference values for normal facial growth are not yet available in this age group (0-6 years). Neither longitudinal three-dimensional facial growth data of cleft patients (age 0-6 years) are available.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

The patient inclusion criteria are non-syndromic UCLP or BCLP. Infants should be born at term (38+ wk) and both parents should be Caucasisch for both the case and control group.

Exclusion criteria

Other congenital malformations and soft tissue bands. In addition no oral clefts have occured in the first, second or third degree relatives of the control child.

Study design

Design

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

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	06-09-2007

Enrollment:	105
Type:	Anticipated

Ethics review

Approved WMO Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL17934.091.07