CLEfts and FEeding Difficulties (CLEFED-2)
The prevalence of feeding difficulties in children with cleft lip and/or palate.

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The purpose of this study is to contribute to the knowledge of feeding problems in infants with CL, CP and CLP. Our evidence based results can help clinicians, involved in the care of cleft patients, in providing proper information and professional...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Congenital and hereditary disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON41195

Source
ToetsingOnline

Brief title
CLEfts and FEeding Difficulties (CLEFED-2)

Condition

- Congenital and hereditary disorders NEC

Synonym
cleft lip, cleft palate

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Fonds NutsOhra

Intervention

Keyword: Clefts, Feeding, Feeding difficulties

Outcome measures

Primary outcome

the main study parameters of this study are:*

- feeding techniques and skills, defined by the Nijmeegse Observatielijst Lepelvoeding (NOL) and SOMA and an observation lists focussed on children with clefts and parent-child interaction.

- weight gain (growth), defined by the difference in measurements (standard deviation) marked on a standardized growth-curve

Secondary outcome

NG feeding (and duration), extent of the cleft palate, associated malformations, upper respiratory infections / pneumonia, medication (child), placement of grommets (middle ear tubes), complications/adverse effects

Study description

Background summary

Many studies have shown that children with clefts are at high risk of developing feeding disorders. Feeding problems can have an adverse effect on growth, and primary protein energy malnutrition can occur. Reports describing feeding skills in CL/P are often contradictory and lacking in detail. The soft palate cleft is generally closed between 6 to maximum 12 months of age. There is no consensus about the exact prevalence of feeding difficulties and the relation of birthweight and growth with clefts.

Study objective

The purpose of this study is to contribute to the knowledge of feeding problems in infants with CL, CP and CLP. Our evidence based results can help clinicians, involved in the care of cleft patients, in providing proper information and professional support and the approach and treatment of feeding disorders; (1) it will give information about the prevalence of feeding difficulties in children with clefts which of course is essential as a starting point in approving adequate professional counseling; e.g. how many children with clefts are subject to feeding disorders? and is there a difference between the different types of clefts? (2) Furthermore this study will prospectively investigate the birth weight and growth of children with clefts in comparison to children without clefts. If seems important to know how the nutritional status of children with clefts is directly after birth and how it develops in the months after. (3) Finally, the parent-child interaction is investigated and related to the interaction of parents and their healty children. This information will significantly contribute to the determination of adequate therapeutic strategies.
Our aim is to do a longitudinal prospective trail. The study population consists of children born with a cleft.

Study design

Prospective longitudinal observational trial

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: *
Patients will visit (45 minutes) the investigator and speech therapist at the age of 4 weeks, 3 and 6 months. Patients will be measured (weight) and observed following the NOL and observation lists. Parents will be interviewed following a questionnaire. It is estimated that the risk related to this research is negligible because; the risk of damage is not greater than the risk of the now current care. There is no risk of occurrence of unknown risks, the physical burden on the child is minimal, the psychological burden for the child and parents is minimal, there are no social risks associated with the investigation.There are no expected risks associated with the study design and implementation. *This research is group related. Children with CL, CLP or CP are essential to answer the research questions. Furthermore, children within this specific age category (minors) are fundamental for this study since feeding is particularly important in early childhood and growth is observed in early life.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Consecutive 70 children (age 0-4 weeks) that visit the cleft-team: - adequate understanding of the Dutch language by the parents - cleft lip
- cleft lip and palate
- cleft palate only
- Informed consent

Exclusion criteria

- previous treatment and follow-up by another cleft-team (another hospital)
- no informed consent
- children that were adopted

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-07-2014
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO Date:	06-05-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	10-11-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL48107.041.14