

How much and which feeding difficulties do we see in children with cleft lip and/or palate?

No registrations found.

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

Summary

ID

NL-OMON24731

Source

NTR

Brief title

CLEFED-2

Health condition

cleft palate, clefts, feeding difficulties, parent child interaction

Sponsors and support

Primary sponsor: University Medical Center Utrecht, The Netherlands

Source(s) of monetary or material Support: Fonds Nuts Ohra

Intervention

Outcome measures

Primary outcome

Feeding problems (techniques and skills)

Birth weight and weight gain

Parent-child interaction

Secondary outcome

- NG feeding incidence (and duration)
- 'Feeding sequelae' (gagging, choking, apnea's , regurgitation)
- Extent of the cleft
- Associated malformations
- Breathing problems
- Upper respiratory infections / pneumonia
- Medication (child)
- Surgical closure of the lip
- Adverse effects/complications

Study description

Background summary

SUMMARY

Rationale: Many studies have shown that children with clefts are at high risk of developing feeding disorders. Early nutritional deficits are linked to long-term impairment in growth, health and development of children. There is no consensus about the prevalence of feeding difficulties in children with clefts. Furthermore, too little is known about the birth weight and growth of children with clefts in comparison to their healthy peers.

Objective: The main objectives of this study are (1) what is the nature and course of nutritional problems in children with cleft lip and palate receiving cleft care following the standard protocol in the Wilhelmina Childrens Hospital, Utrecht, The Netherlands? (2) are children with clefts significantly more underweight than healthy children between 0 and 6 months of age? (3) is there a difference in the parent-child interaction in comparison to healthy children? Secondary objectives are nasogastric (NG) feeding, 'feeding sequelae', extent of the cleft, associated malformations, breathing problems, upper respiratory infections / pneumonia, medication (child), surgical closure of the lip, adverse effects/complications.

Study design: longitudinal prospective descriptive study

Study population: Consecutive 70 children (age 0-6 months) born with cleft lip (CL) cleft lip and palate (CLP) or cleft palate only (CP), seen at the cleft-team of the Wilhelmina Children's Hospital in Utrecht, The Netherlands.

Intervention: there will be no use of an investigational treatment.

Main study parameters/endpoints: The main study parameter is feeding technique and skills, most importantly defined by the 'Nijmeegse Observatielijst Lepelvoeding' (NOL), 'Schedule from Oral-Motor Assessment' (SOMA) and the observation list feeding skills. In addition weight gain (growth), is studied, and defined by the difference in measurements (standard deviation) marked on a standardized growth-curve. The parent-child interaction is defined by the observation-list parent-child interaction.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients will be seen (during 45 minutes) by the investigator and speech therapist at the age of 4 weeks, 3 and 6 months at home. Patients will be measured (weight) (and the parents will be interviewed) and will be observed. It is estimated that the risk related to this research is negligible because the risk of complications is not greater than the risk of the current care. There is no risk of occurrence of unknown risks. The physical and psychological burden for the child and parents is minimal and there are no social risks associated with the investigation. Furthermore 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.

Study objective

Many studies have shown that children with clefts are at high risk of developing feeding disorders. Especially children with a cleft lip and palate (CLP) or cleft palate only (CP) are subject to feeding disorders. 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

Study design

Observation of feeding at 4 weeks, 3 months and 6 months of age.

Intervention

None

Contacts

Public

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Eligibility criteria

Inclusion criteria

Consecutive 70 children with a cleft (age 0-4 weeks) that visit the cleft-team:

- adequate understanding of the Dutch language by the parents
- (expressed (gekolfde)) breast and bottle feeding
- cleft lip
- cleft lip and palate - cleft palate only
- Informed consent

Exclusion criteria

Patients cannot participate in this study if they meet one or more of the following 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
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	09-06-2014
Enrollment:	70
Type:	Anticipated

Ethics review

Positive opinion	
Date:	23-05-2014
Application type:	First submission

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
NTR-new	NL4378
NTR-old	NTR4592
Other	METC : 14-149/M

Study results