

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

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	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

## **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 then 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

Division of Pediatric Plastic Surgery<br>  
Wilhelmina Children's Hospital<br>  
University Medical Center Utrecht<br>  
P.O.Box 85090<br>  
KE.04.140.0  
I.A.C. Vries, de  
Utrecht 3508 AB  
The Netherlands  
+31 (0)88 7554004

### Scientific

Division of Pediatric Plastic Surgery<br>  
Wilhelmina Children's Hospital<br>  
University Medical Center Utrecht<br>  
P.O.Box 85090<br>  
KE.04.140.0  
I.A.C. Vries, de  
Utrecht 3508 AB  
The Netherlands  
+31 (0)88 7554004

## 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