

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

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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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24731

Bron

NTR

Verkorte titel

CLEFED-2

Aandoening

cleft palate, clefts, feeding difficulties, parent child interaction

Ondersteuning

Primaire sponsor: University Medical Center Utrecht, The Netherlands

Overige ondersteuning: Fonds Nuts Ohra

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Feeding problems (techniques and skills)

Birth weight and weight gain

Parent-child interaction

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

None

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	09-06-2014
Aantal proefpersonen:	70
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	23-05-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4378
NTR-old	NTR4592
Ander register	METC : 14-149/M

Resultaten