CLEfts and FEeding Difficulties (CLEFED-1): the effect and timing of surgical closure in children with cleft palate.

Published: 10-01-2012
Last updated: 01-05-2024

The main objectives of this study are feeding techniques and skills and weight gain. Secondary objectives are NS feeding *feeding sequelae*, extent of the cleft, associated malformations, upper respiratory infections / pneumonia, medication (child...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Congenital and hereditary disorders NEC
Study type	Interventional

Summary

ID

NL-OMON39509

Source
ToetsingOnline

Brief title
CLEFED-1

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, Surgical closure

Outcome measures

Primary outcome

Main study parameters/endpoints: the main study parameters of this study are:

- feeding techniques and skills, defined by scores from Montreal Children*s Hospital Feeding scale (MCH), Nijmeegse Observatielijst Lepelvoeding (NOL) and an observation lists focussed on children with clefts.

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

Secondary outcome

Secondary parameters/endpoints: NS 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 currently closed between 6 to maximum 12 months of age. No studies have been indentified that examined the relation of surgical closure of the cleft and the effect of this repair on feeding (difficulties).

Study objective

The main objectives of this study are feeding techniques and skills and weight gain. Secondary objectives are NS feeding *feeding sequelae*, extent of the cleft, associated malformations, upper respiratory infections / pneumonia, medication (child), placement of grommets (middle ear tubes), adverse effects/complications.

Study design

Study design: Randomized controlled intervention trial

Intervention

Intervention: One group will undergo surgical closure between the age of 6-8 months and the other group between the age of 10-12 months. All patients will undergo this intervention following the standard, current protocol.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
All patient will undergo surgical intervention following the standard, current protocol. Patients will be visited (45 minutes) by the investigator/speech therapist at the age of 6,9,13 and 17 months. Patients will be measured (weight) and observed following the NOL and observation lists. Parents will be interviewed following a questionnaire and the MCH-scale. 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, the burden of the operation is equal to current concerns. 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 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 children will undergo the surgical closure of the cleft within the first year after birth.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Childeren born with a cleft lip and palate or cleft palate that visit the cleft team. Inclusion at the age of 5 months.
Adequate understanding of the Dutch language by the parents
Informed consent

Exclusion criteria

Children that were adopted
Children that are previous seen by another cleft-team (another hospital)
No informed consent

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-04-2012
Enrollment:	240
Type:	Actual

Ethics review

Approved WMO Date:	10-01-2012
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	20-12-2013
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	07-11-2014
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	26-01-2017
Application type:	Amendment
Review commission:	METC NedMec

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	NL37862.041.11
Other	NTR (TC = 3275)