Parent-child relationship, cognitive development and social-emotional functioning in children with intestinal failure;(PICASsO-study = Pediatric Intestinal failure: Cognitive And Social-emotional Outcomes)

Published: 16-05-2019
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(1) To assess parent-child attachment and interaction in a cohort of children and adolescents known with IF and (a history of) home PN dependence, and (2) to assess cognitive development and social-emotional functioning in these children.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal tract disorders congenital
Study type	Observational non invasive

Summary

ID

NL-OMON54827

Source
ToetsingOnline

Brief title
PICASsO-study

Condition

- Gastrointestinal tract disorders congenital
- Gastrointestinal conditions NEC
- Gastrointestinal therapeutic procedures

Synonym
intestinal failure / chronic intestinal failure

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: intestinal failure, neurodevelopment, parent-child interaction, psychosocial

Outcome measures

Primary outcome

Disturbed parent-child attachment and interaction, measured by the Attachment Insecurity Screening Inventory (AISI), Emotional Availability Scales (EAS) and the Parent-Child Interaction Questionnaire-Revised (PACHIQ-R).

Secondary outcome

Cognitive impairment and social-emotional problems, measured by age attuned psychological instruments.

Study description

Background summary

The last decades, parenteral nutrition (PN) treatment in multidisciplinary teams has tremendously improved intestinal failure (IF) survival rates and decreased complications. Therefore, new challenges become apparent, concerning cognitive development, social-emotional aspects and parent-child relationship. Secure attachment is thought to be the basis for future psychosocial competence, and is associated with better cognitive development in later life. We hypothesize that a disturbed parent-child relationship is common in children with IF, since these children are hospitalized for a great part of their childhood with multiple caregivers and changes in parental roles. Parent-child interaction may be challenged even more in children with IF depending on PN, due to the presence of major feeding problems. In early life, the process of feeding and the interaction and contact between parent and child during feeding

is very important in the development of attachment. Diminished (oral) feeding opportunities disturb parent-child bonding. Also, after hospital admission, parents are trained to do all the required complex medical treatments at home, including administration of the PN and emergency care of the central venous line (CVL). This demanding daily medical care can pressurize the parent*s role in a child*s development.
Furthermore, in studies of children with chronic diseases, congenital gastrointestinal disorders and preterm birth - which have aspects in common with children with IF - it was shown that they have impaired cognitive development and social-emotional problems at a later age. We expect to find this in children with IF too, maybe even to a larger extent because of multiple line infections (affecting the brain), limited freedom of movement due to the PN (impeding exploratory play), and experiencing (social) mealtimes differently.

Study objective

(1) To assess parent-child attachment and interaction in a cohort of children and adolescents known with IF and (a history of) home PN dependence, and (2) to assess cognitive development and social-emotional functioning in these children.

Study design

Cross-sectional observational cohort study. Age-specific psychological questionnaires, interviews and observations will take place to assess parent-child attachment and interaction, cognitive development, and social-emotional functioning in children and adolescents with IF. Also, the Pediatric Quality of Life Inventory Gastrointestinal module (PedsQL GI) will be filled out to evaluate feeding problems and gastrointestinal complaints.

Study burden and risks

The risks of participating in the study are negligible. Children and/or their parents will be asked to fill out five to six questionnaires, taking one and a half hour in total to complete. A psychological interview and observation will take place and a cognitive test will be done, taking four and a half hours in total. There is some burden of participating in the study, since all investigations are not part of standard care, cost time, and can be mentally demanding. However, children will be investigated for study purposes during standard outpatient clinic visits as much as possible, so no extra visits are required. Parents will be compensated for travel expenses and children will receive a study present. Also, if necessary based on the results of the psychological assessment, children (and their parents) will be offered appropriate treatment and guidance. In this way, individual participants may directly benefit from participating. When we indeed find increased parent-child

interaction problems in our pediatric IF population, we can in the future take early necessary measures and offer guidance to parents and children with IF. Hereby we help vulnerable children and their parents, to prevent cognitive and psychosocial problems later in life.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Babies and toddlers (28 days-23 months)

Inclusion criteria

1. Children known with intestinal failure, who receive parenteral nutrition at home and therefore (regularly) visit the outpatient clinic of the multidisciplinary intestinal failure team of the Erasmus MC Sophia Children*s

Hospital (Rotterdam) or Amsterdam UMC Emma Children's Hospital (Amsterdam).
2. Children previously dependent on parenteral nutrition at home in the past and now still visiting the outpatient clinic of the multidisciplinary intestinal failure team or the CHIL (surgical long term follow up) of the Erasmus MC Sophia Children*s Hospital for feeding difficulties or regular follow up.

Exclusion criteria

- Participation in an intervention study, interfering with the primary outcome of this study
- Absence of written informed consent
- Insufficient knowledge of the Dutch language of the parents/caregivers and participants (if older than 12 years)

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):	05-09-2019
Enrollment:	116
Type:	Actual

Ethics review

Approved WMO

Date:	16-05-2019
Application type:	First submission

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	31-08-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-08-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-08-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL67145.078.19