Long-term monitoring of children with intestinal failure

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To investigate the relationship between body composition and parenteral nutrition in children with intestinal failure at 6 months corrected age. The ultimate goil of this study is to optimize the treatment of children with intestinal failure by…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal tract disorders congenital
Study type	Observational invasive

Summary

ID

NL-OMON53046

Source
ToetsingOnline

Brief title
Intestinal failure in children - Trompet study

Condition

- Gastrointestinal tract disorders congenital
- Gastrointestinal conditions NEC

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: er worden op dit moment fondsen aangeschreven

Intervention

Keyword: Body composition, Growth, Intestinal failure, Parenteral nutrition

Outcome measures

Primary outcome

To assess if body composition (defined by %BF) at 6 months corrected age is associated with amount of PN provided (time-weighted area under the curve for % of total kilocalories provided by PN and duration of PN) until 6 months corrected age.

Secondary outcome

Secondary study parameters: growth (weight, length/height, head circumference and calculated SD scores), bone health (bone mineral density, bone mineral content, and bone mineral apparent density, bone age and bone health index), other complications of parenteral nutrition (line sepsis, liver disease). Insufficient gut mass (citrulline), epithelial damage (urinary I-FABP), appetite regulation (ghrelin), intestinal homeostasis (16s ribosomal RNA, CD4/CD8 T-cells, B-cells, NK-cells and neutrophil granulocytes (blood) and levels of calprotectin, presence of neutrophil granulocytes, secretory IgA and description of the microbiome (stool)).

Study description

Background summary

Intestinal failure is defined as a critical reduction of the gut mass or its function below the minimum needed to absorb nutrients and fluids required for adequate growth and development in children. The aims in the management of children with intestinal failure are threefold; 1) maintaining growth and

development, 2) promoting intestinal adaptation, 3) preventing complications. Children with intestinal failure are receiving parenteral nutrition, which is associated with frequent complications, including impaired growth, decreased bone mineral density and altered body composition with increased fat mass and decreased fat free mass. The course of growth and body composition has not been investigated starting from the diagnosis onwards and the relationship between parenteral nutrition, growth and body composition is not yet clear. Measurement of growth, bone health and body composition from diagnosis onwards would therefore provide important information on nutritional needs of these children and long-term effects of parenteral nutrition.
The overall goal in the treatment is to decrease and eventually stop the parenteral nutrition. Current practice during this process is mostly *trial and error* and there is no convenient marker to predict whether patients will be able to wean off parenteral nutrition. The most important factor that is delaying the process of decreasing parenteral nutrition is intolerance to enteral nutrition. It is thought that insufficient gut mass, epithelial damage, intestinal inflammation, impaired gastrointestinal motility and appetite may play a role in intolerance to enteral nutrition. Gaining insight in these parameters of influence would be very helpful in achieving intestinal autonomy in these children. We hypothesize that children with intestinal failure who have more parenteral nutrition have altered body composition, poorer growth and bone health compared to children with intestinal failure already weaned off parenteral nutrition or children with less parenteral nutrition. Furthermore, we want to gain insight in the parameters of influence in weaning of parenteral nutrition. With this study we want to add knowledge on how to improve the treatment of children with IF in all three areas (maintaining growth, promoting intestinal adaptation and preventing complications) in order to facilitate the best long-term management and prognosis.

Study objective

To investigate the relationship between body composition and parenteral nutrition in children with intestinal failure at 6 months corrected age. The ultimate goil of this study is to optimize the treatment of children with intestinal failure by adjusting the parenteral nutrition individually with optimal growth and body composition and as little complications as possible.

Study design

Prospective, observational cohort study.

Study burden and risks

The PEA POD® is a registered product that we will use for its original purpose; measuring body composition in neonates and infants. No adverse events have been reported regarding the use of PEA POD®. The PEA POD® showed to be accurate and

feasible, with a limited test time and a warmed test chamber. The infant can be observed through the window by the investigator, and the parents are able to watch their child through the window as well. Furthermore, the PEA POD® has a safety system, consisting a Cancel Test button and an Emergency STOP button that ends the test immediately. The PEA POD® is used in the Sophia Children*s Hospital for several years. Until now a total of 320 infants have been investigated without any adverse events (MEC- 2012-444, MEC-2012-164 and MEC-2014-379). Blood samples will be taken from indwelling lines placed or in addition to blood drawings for clinical reasons. The risks associated with the withdrawal of extra blood can be considered negligible and the burden will be minimal. Assessments during follow-up will be performed at standard-care outpatient clinic visits as much as possible.

In addition, healthy children (children of colleagues) will be asked for the collection of the stool, this will be done twice and can be done at home.

Furthermore, children known with intestinal failure, but not dependent on home parenteral nutrition anymore (attending the intestinal failure team at the Sophia Children's Hospital) will be asked for the collection of stool samples. This will be done twice and can be brought to the appointment at the outpatient clinic.

At the time of body composition measurement, a questionnaire on physical activity will be filled in by the children/their parents.

Parents of healthy infants will be asked to collect one stool sample as a comparison for infants with intestinal failure.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)
Babies and toddlers (28 days-23 months)
Newborns
Premature newborns (<37 weeks pregnancy)

Inclusion criteria

Children, newly diagnosed with intestinal failure in the Erasmus MC-Sophia Children*s Hospital. Three groups of children will be included:
1. Children with congenital gastro-intestinal anomalies with involvement of the small intestine, independent of expected use of parenteral nutrition.
2. Neonates with an expected use of parenteral nutrition >= 1 week after a gastrointestinal intervention (laparotomy).
3. Children with a (suspected) motility disorder or intrinsic disorder of the intestinal mucosa (enteropathy) with an expected use of parenteral nutrition > 2 weeks and children with an expected use of parenteral nutrition >= 1 week after a gastrointestinal intervention (laparotomy) after the neonatal period.
In addition, all children already known with intestinal failure and dependent on home parenteral nutrition are eligible for this study (attending the intestinal failure team at the Sophia Children's Hospital and Emma Children's Hospital).
Next to this, healthy children will be asked for the collection of stool samples (children of colleagues).
Furthermore, children known with intestinal failure, but not dependent on home parenteral nutrition anymore (attending the intestinal failure team at the Sophia Children's Hospital) will be asked for the collection of stool samples.
Also, parents of healthy infants will be asked for the collection of stool samples as comparison for the newly diagnosed infants with potential intestinal failure. In addition to this, infants undergoing inguinal hernia repair (who are often born preterm) will be asked for collection of stool samples, also as comparison.

Exclusion criteria

A (potential) subject who meets any of the following criteria will be excluded from participation in this study:
- Participating in an intervention study, interfering with 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 invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-03-2015
Enrollment:	245
Type:	Actual

Ethics review

Approved WMO Date:	02-03-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-08-2015

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	27-07-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	31-08-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-10-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	02-05-2022
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	NL51311.078.14