Long-term monitoring of children with intestinal failure

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27840

Source
NTR

Brief title
Trompet study

Health condition

Intestinal failure; body composition; growth; bone health.

Sponsors and support

Primary sponsor: Erasmus Medical Center - Sophia Children's Hospital
Source(s) of monetary or material Support: Erasmus Medical Center - Sophia Children's Hospital

Intervention

Outcome measures

Primary outcome

Body composition measured, defined by %BF
Parenteral nutrition (time-weighted area under the curve for % of total kilocalories provided by parenteral nutrition and duration of PN)

Secondary outcome

Growth, defined by weight, length, head circumference and calculated SD scores. Mid-upper arm circumference scores.
Bone health, defined by bone mineral density (g/cm2), bone mineral content (g) and bone mineral apparent density (g/cm3), bone age and bone health index.

Study description

Background summary

In this prospective, observational study we investigate the relationship between body composition, growth and parenteral nutrition in children with intestinal failure. In addition, we investigate the bone health of children with intestinal failure.

Study objective

Children with intestinal failure who receive a profound percentage of total kilocalories by parenteral nutrition for aprolonged period have altered body composition, poorer growth and bone health compared to children with intestinal failure off parenteral nutrition or children with less parenteral nutrition.

Study design

The duration of the study for each subject will last two years. There will be 12 visits during this study, but only when the patient is admitted or visiting the outpatient clinic. For children already known with intestinal failure, there will be 8 visits.

Intervention

N/A

Contacts

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Eligibility criteria

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 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.

Furthermore, children already known with intestinal failure who receive parenteral nutrition at home and visit the intestinal failure outpatient clinic will be included, both in the Erasmus MC - Sophia Children's Hospital and the AMC - Emma Children's Hospital.

Exclusion criteria

Participating in an intervention study, interfering with primary outcome of this study.

Absence of written informed consent

Insufficient knowledge of the Dutch language

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2015
Enrollment:	62
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	01-09-2016
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	NL5892
NTR-old	NTR6080
Other	MEC : 2015-002

Study results