

Long-term monitoring of children with intestinal failure

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

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

Samenvatting

ID

NL-OMON27840

Bron

NTR

Verkorte titel

Trompet study

Aandoening

Intestinal failure; body composition; growth; bone health.

Ondersteuning

Primaire sponsor: Erasmus Medical Center - Sophia Children's Hospital

Overige ondersteuning: Erasmus Medical Center - Sophia Children's Hospital

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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)

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

Children with intestinal failure who receive a profound percentage of total kilocalories by parenteral nutrition for a prolonged 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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Absence of written informed consent

Onderzoeksopzet

Opzet

Type: Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel: Anders
Controle: N.v.t. / onbekend

Deelname

Nederland
Status: Werving gestart
(Verwachte) startdatum: 01-03-2015
Aantal proefpersonen: 62
Type: Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies
Datum: 01-09-2016
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	NL5892
NTR-old	NTR6080
Ander register	MEC : 2015-002

Resultaten