Double-blind, parallel, randomised study to investigate the effect of an energy- and protein-enriched formula on whole body protein turnover, substrate utilization, growth and tolerance in mechanically ventilated, critically ill infants.

Gepubliceerd: 01-11-2005 Laatst bijgewerkt: 18-08-2022

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24240

Bron
NTR

Verkorte titel
Infatrinistudie

Ondersteuning

Primaire sponsor: Nutricia Netherlands

Participants Nutricia Netherlands:
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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Whole body protein metabolism on day 4;
2. Rate of protein synthesis;
3. Rate of protein breakdown;
4. Rate of protein oxidation;
5. Rate of net nitrogen accretion.

Toelichting onderzoek

Achtergrond van het onderzoek

Adequate nutrition is essential part of threatment of critically ill infants and children but often receives little attention in the acute phase of the disease. Undernutrition however is present in 15-20% of all children admitted to pediatric intensive cares. Undernutrition is associated with decreased woundhealing, decreased immunefunction and increased mortality and morbidity. Requirements of critically ill infants and children are not known.

In the present study we investigate the requirement of these children by comparing an energy and protein enriched infant formula (Infatrini, Nutricia, Zoetermeer, The Netherlands) with the standard infant formula (Nutrilon 1, Nutricia, Zoetermeer Netherlands) during 7 days in a randomised double blind manner. Our hypothesis is that the protein and energy enriched formula has positive effects on protein metabolism (as measured with stable isotope methods on the 4th day of enteral nutrition), substrate utilization (daily indirect calorimetry), and growth (body weight, knee-heel length, skinfolds day 1, 4 and 7)) during critical illness and does not lead to overfeeding gewichtsgroei.

Doel van het onderzoek

The hypothesis is that increasing energy and protein intake in these children will stimulate the rate of protein synthesis, decrease the rate of (muscle)protein breakdown, lead to increased net protein accretion, avoids weight loss and promotes growth. The second hypothesis is that it will be well tolerated by these infants and not lead to sign and symptoms of overfeeding. Also the caloric intake achieved with these feeding regimen compared to the energy expenditure will be assessed.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Energy and protein enriched enteral feeding; Infatrini (Nutricia, Zoetermeer, The Netherlands).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age: 1 week – 12 months At term, or born pre-term (before 37 completed weeks of gestation) but > 40 weeks post-conceptional age;

2. Primary admitted to or referred to the Paediatric Intensive Care Units (PICU) of the :1) Sophia Children’s Hospital
or 2) University hospital Maastricht;

3. Respiratory insufficiency due to respiratory disease (viral or bacterial pneumonia);

4. Possibility to start study within 24 hours after admission;

5. Mechanical ventilation;

6. Expected length of stay >72 hours;
7. Exclusively formula-fed;

8. Naso-duodenal/gastric feeding during the study period;

9. No contra-indication for enteral nutrition Haemodynamic stable condition (normal, stable blood pressure and normal renal function);

10. One venous and one arterial line present;

11. Written informed consent from a parent or legal guardian.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Simultaneous participation in another clinical study with interventions that may influence the end points of this trial;

2. Breastfeeding;

3. Known chromosomal disorder;

4. Congenital GI obstructions (duodenal atresia, anal atresia etc.), congenital metabolic disease, abnormal liver or kidney function tests, active upper GI bleeding or postoperative ileus;

5. At risk for intestinal ischaemia (to the judgement of the paediatric intensivist – including hypoxia and shock).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel

Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	12-01-2003
Aantal proefpersonen:	24
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	01-11-2005
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	NL474
NTR-old	NTR515
Ander register	: N/A
ISRCTN	Incomplete data for ISRCTN

Resultaten

Samenvatting resultaten
N/A