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.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24240

Source
NTR

Brief title
Infatrinistudie

Sponsors and support

Primary sponsor: Nutricia Netherlands

Participants Nutricia Netherlands:
Mrs. C. Kleijer Nutricia Netherlands, Scientific Services
P.O. Box 1
2700 MA Zoetermeer, The Netherlands
Tel: 0031-79-3539205/452
E-mail: chantal.kleijer@nutricia.nl

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

1. Differences in energy and substrate utilization (indirect calorimetry);

2. Gastric retentions as a measure of tolerance of the different feedings;

3. Protein and caloric intake achieved on on day 4;

4. Growth on day 4 and 7;

5. Weight gain;

6. Length gain (knee-heel length);

7. Skinfold + arm circumference.

Study description

Background summary

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.

Study objective

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.

Study design

N/A

Intervention

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

Contacts

Public
D.A Waardenburg van
Department of Paediatrics,
Paediatric Intensive Care
[default]
The Netherlands
+31-43-3875245
Scientific
D.A Waardenburg van
Department of Paediatrics,
Paediatric Intensive Care
[default]
The Netherlands
+31-43-3875245

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-01-2003
Enrollment:	24
Type:	Actual

Ethics review

Positive opinion

Date:	01-11-2005
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	NL474
NTR-old	NTR515
Other	: N/A
ISRCTN	Incomplete data for ISRCTN

Study results

Summary results
N/A