Nutritional Intervention for Preterm Infants-2

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20272

Source
Nationaal Trial Register

Brief title
NIPI-2

Health condition

Preterm neonates, Premature infants, parenteral nutrition, tolerance

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

Nitrogen balance

Secondary outcome

1. Safety of the nutritional regimen: as reflected by normal blood chemistry, no effect on hearing ability, no effect on chronic lung disease;

2. Growth: measured in terms of body weight, knemometry, head circumference, protein accretion and protein breakdown;

3. Fatty acid profile in plasma and erythrocytes;

4. Energy expenditure;

5. Short- and long-term outcome: days on mechanical ventilation, incidence of bronchopulmonary dysplasia, incidence of infection, intraventricular hemorrhage, and necrotizing enterocolitis, normal ALGO-test and Bayley III scores

Study description

Background summary

After birth, premature infants mainly depend on their limited endogenous stores and on parenteral nutrition for energy and growth. However, the optimal amounts and composition of the exogenous nutrients is not known. Recently, we demonstrated the beneficial effect of early amino acid (AA) supplementation on nitrogen balance, protein synthesis and redox state. Early lipid administration, in addition to amino acids and glucose, may be beneficial, since it provides energy for enhanced protein accretion and supplies essential fatty acids necessary for central nervous system development. With this study, we will quantify the effect of early parenteral lipid introduction and additional amino acid supplementation on protein accretion and growth, and determine possible adverse effects. Initiating total parenteral nutrition in an earlier stage after birth and in a different composition, as in this study, can further improve early postnatal outcome.
In addition we will compare different fat emulsions.

Study objective

Early lipid and extra amino acid administration is safe and effective and leads to improved short- and long-term outcome.

Study design

Most outcome measurements will be registered during the first week of life (nitrogen balance, safety, fatty acid profile, protein metabolism and energy expenditure), growth will be recorded during the first five weeks of life, and general short- and long-term outcome will be recorded until two years corrected age.

Intervention

Intervention group A will receive lipids from birth onwards. Interventiongroup B will receive extra amino acids in combination with lipids from birth onwards. The control group will be fed according to the standard nutrition policy (lipids from day 2 or 3 onwards). Different lipid emulsions will be compared.

Contacts

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Eligibility criteria

Inclusion criteria

1. Inborn, Gestational weight less than 1500g

Exclusion criteria

1. Congenital anomalies

2. Metabolic disease

3. Endocrine, renal or hepatic disorder

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	06-10-2008
Enrollment:	240
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-09-2008
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	NL1385
NTR-old	NTR1445
Other	METC Erasmus MC : MEC-2008-186
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A