

Nutritional Intervention for Preterm Infants II

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Evaluation of the effects of intravenous lipid and extra amino acid supplementation from birth onwards to very low birth weight infants on amino acid turnover and protein accretion. As secondary objectives the safety, energy expenditure and short-...

Ethical review	-
Status	Recruitment stopped
Health condition type	Neonatal and perinatal conditions
Study type	Interventional

Summary

ID

NL-OMON35546

Source

ToetsingOnline

Brief title

NIPi II

Condition

- Neonatal and perinatal conditions

Synonym

preterm infants, very low birth weight infants

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Sophia BV

Intervention

Keyword: amino acids, lipids, parenteral nutrition, preterm infants

Outcome measures

Primary outcome

Nitrogen balance

Secondary outcome

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

Growth: measured in terms of body weight, protein accretion and protein breakdown

Fatty acid profile in plasma and erythrocytes, plasma phytosterol profile

Energy expenditure

Short- and long-term outcome: days on mechanical ventilation, incidence of bronchopulmonary dysplasia, incidence of infection, incidence of intraventricular hemorrhage, incidence of necrotizing enterocolitis, normal ALGO (screening for hearing loss), brain growth and development at 30 and 40 and/or 46 weeks gestational age and Bayley III scores (Mental Developmental Index and Psychomotor Developmental Index) at 2 years of age (corrected age for gestational age).

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 would like to compare two different fat emulsions (Intralipid 20% en SMOFlipid 20%).

Study objective

Evaluation of the effects of intravenous lipid and extra amino acid supplementation from birth onwards to very low birth weight infants on amino acid turnover and protein accretion. As secondary objectives the safety, energy expenditure and short- and long-term outcome will be investigated.

Study design

Single-centred, randomized, prospective trial with open label

Intervention

The intervention group 1 will receive lipids from birth onwards. Intervention group 2 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 3 onward). Half of the infants in the intervention groups will receive Intralipid 20%, the other half SMOFlipid 20%.

Study burden and risks

Within the general study, two isotope substudies are performed. In substudy 1, amino acid stable isotopes are infused via a venous catheter and blood samples are withdrawn from an arterial catheter (both in situ for medical reasons). In addition, expiratory air is collected. The child will hardly notice this. In

substudy 2, doubly labeled water (stable isotopes) will be infused and saliva samples will be collected to evaluate energy expenditure. In addition, in 10 ventilated infants per group energy expenditure will be analyzed with indirect calorimetry as well. In all included infants urine samples will be collected as well on two separate days. Extended experience with the use of stable isotopes in extreme premature infants has not shown side effects.

We hypothesize that patients who receive total parenteral nutrition from birth onwards have an improved nutritional status and growth, and better clinical outcome.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Children (2-11 years)

Inclusion criteria

Born within the Sophia Children's Hospital

Birth weight less than 1500g

Written informed consent

Exclusion criteria

Congenital anomalies

Metabolic disease

Endocrine, renal or hepatic disorder

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	22-12-2008
Enrollment:	240
Type:	Actual

Ethics review

Approved WMO	
Date:	28-11-2008
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	
Date:	26-03-2009

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-02-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	06-09-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL21277.078.08