Threonine requirement in preterm neonates

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The aim of the study is to quantify the requirement of threonine in preterm infants. We hypothesize that the current estimations for preterms are too high.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Protein and amino acid metabolism disorders NEC
Study type	Interventional

Summary

ID

NL-OMON36663

Source
ToetsingOnline

Brief title
Threonine-preterm

Condition

- Protein and amino acid metabolism disorders NEC

Synonym
requirement of one of the essential amino acids, threonine requirement

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Danone Vitapole,Sophia BV

Intervention

Keyword: amino acid requirement, IAAO methode, neonates, threonine

Outcome measures

Primary outcome

We will test the requirement of threonine by breakpoint estimation. This will

be determined by applying a two-phase linear regression model.

Secondary outcome

not applicable

Study description

Background summary

The exact requirement of essential amino acids for term and preterm neonates is not known. So far, requirements have been estimated either from the composition of human milk or are derived using nitrogen balance studies which are known to be imprecise. By using a new method, the indicator amino acid oxidation (IAAO), we are able to determine the exact individual requirement for all essential amino acids in both term and preterm infants. This will improve our knowledge on how to feed infants and might improve functional outcome in these vulnerable patient groups. We recently determined the requirement of the branched chain amino acids valine, isoleucine and leucine in Asian term neonates. The requirement of valine and isoleucine showed to be two fold higher than current recommendations.

Study objective

The aim of the study is to quantify the requirement of threonine in preterm infants. We hypothesize that the current estimations for preterms are too high.

Study design

This will be a randomized, unblinded, non-therapeutic intervention study. It will be a multicenter trial performed in the Erasmus MC-Sophia, the Sint Francisus Hospital, the Maasstad Hospital (all Rotterdam), the Albert Schweitzer Hospital Dordrecht, the Amphia Hospital Breda and the Haga Hospital in The Hague.The study will start September 2011 and will last for 2 years.

Intervention

The subjects will adapt for 24 hours to the study formula. At the study day, subjects will receive a primed (15 µmol/(kg) continuous (10 µmol/(kg•h)) enteral infusion of [13C]bicarbonate for 2.5 h to quantify individual CO2 production. An elemental diet (Neocate®, Numico) will be used to provide the infants with different amino acid intakes. The labeled sodium bicarbonate infusion will be directly followed by a primed (40 µmol/(kg)) continuous (30 µmol/(kg•h)) enteral infusion of [1-13C]-Lysine for four hours. 30 minutes before start of the oxidation study the feeding regimen will be changed into continuous drip-feeding. Enterally infused tracer will be mixed with the study formula and infused continuously by an infusion pump via the nasogastric tube. Breath samples will be obtained using the direct sampling method described by Van der Schoor et al. (1). Briefly, a 6 Fr gastric tube (6 Ch Argyle; Cherwood Medical, Tullamore, Ireland) will be placed 1 to 1.5 cm into the nasopharynx and end-tidal breath will be taken slowly with a syringe connected at the end. Baseline samples will be obtained 15 and 5 minutes before starting tracer infusion. During the experiment duplicate 13C-enriched breath samples will be collected every 10 minutes during the last 45 minutes of the [13C]bicarbonate infusion and the last hour of the [1-13C]-lysine infusion

Study burden and risks

The children eligible for our study are already warded at the Department of Neonatology of the participating centers. All preterm babies already have a nasogastric tube as a standard procedure.We will insert a tube 1-1.5 cm. in the nasopharynx to obtain the air samples. Although the insertion might give some discomfort since the tube will be fixed, we did not notice any discomfort in our ample experience. We have already performed this procedure in more than 300 infants. In all studies done with stable isotopes in premature neonates, no side-effects were seen. We expect there are no risks and no benefits for the included children.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Preterm infants with a gestational age of 30-35 weeks and a birth weight of less than 2200 grams
Fully enterally fed prematures with a postnatal age < 28 days.
Weight gain rate > 10 g/kg/d in preceding 5 days

Exclusion criteria

Congenital anomalies
Sepsis
Gastro-intestinal pathology

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-05-2012
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	24-01-2011
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	22-11-2011
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	21-02-2012
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	24-05-2012
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 26530
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL31220.000.10
OMON	NL-OMON26530