The threonine requirement in preterm neonates. De behoefte aan threonine in de voeding van de preterm geboren neonaat.

No registrations found.

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

Summary

ID

NL-OMON26530

Source
NTR

Brief title
Threonine requirement in preterm neonates

Health condition

neonates, preterms, LBWI, nutrition, amino acids
neonaten, prematuren, voeding, aminozuren

Sponsors and support

Primary sponsor: Erasmus MC Sophia BV
Source(s) of monetary or material Support: Danone Research BV
SHS International

Intervention

Outcome measures

Primary outcome

The mean requirement of threonine in preterm neonates by breakpoint estimation. This will be determined by applying a two-phase linear regression crossover model.

Secondary outcome

N/A

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.

Study objective

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

Study design

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.

Intervention

The subjects will adapt 24 hours to the study diet. An elemental diet (Neocate®, Danone) will be used to provide the infants with different amino acid intakes.

On the study day subjects will receive a primed (15 µmol/(kg) continuous (10 µmol/(kg•h)) enteral infusion of [13C]bicarbonate by the nasogastric tube for 2.5 h to quantify individual CO_2 production. 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.

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Eligibility criteria

Inclusion criteria

Preterm infants with a gestational age of 30-35 weeks, a postnatal age of 28 days and a birth weight of less than 2200 gram.

Exclusion criteria

1. Congenital anomalies;

2. Sepsis;

3. Gastro-intestinal pathology;

4. No informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-12-2011
Enrollment:	35
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-12-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 36663
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3031
NTR-old	NTR3179
CCMO	NL31220.000.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36663

Study results

Summary results

Lysine requirement of the enterally fed term neonate in the first month of life.
Huang L, Hogewind-Schoonenboom JE, de Groof F, Twisk JW, Voortman GJ, Dorst K, Schierbeek H, Boehm G, Huang Y, Chen C, van Goudoever JB
Am J Clin Nutr. 2011 Dec;94(6):1496-503.