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

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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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26530

Bron
Nationaal Trial Register

Verkorte titel
Threonine requirement in preterm neonates

Aandoening

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

Ondersteuning

Primaire sponsor: Erasmus MC Sophia BV
Overige ondersteuning: Danone Research BV
SHS International

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Congenital anomalies;

2. Sepsis;

3. Gastro-intestinal pathology;

4. No informed consent.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	08-12-2011
Aantal proefpersonen:	35
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	06-12-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 36663
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
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.