

De behoefte aan essentiële aminozuren in pasgeborenen.

No registrations found.

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

Summary

ID

NL-OMON23002

Source

Nationaal Trial Register

Brief title

N/A

Health condition

healthy preterm and term neonates which are growing well
relatief gezonde premature en a terme neonaten die een goede groei vertonen

Sponsors and support

Primary sponsor: Erasmus Sophia BV

Source(s) of monetary or material Support: Danone/Numico/SHS

Intervention

Outcome measures

Primary outcome

Requirement of the 9 essential amino acids determined by the breakpoint.

Secondary outcome

1. Length of adaptation time;
2. validation of the breath sampling compared to urine and blood sampling.

Study description

Study objective

The current estimations of the essential amino acids in neonates are inadequate. We hypothesise these are too low.

Study design

On the studyday breath sampling at start of the study and at isotopic plateau every 15 minutes.

Intervention

Indicator Amino Acid Oxidation (IAAO).

Method: In short:

stable isotope by nasogastric tube
test essential amino acid in wide range of intake for 24 hours adaptation and 8 hours on study day.

Breath sampling for labelled CO₂.

Contacts

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Scientific

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Eligibility criteria

Inclusion criteria

Preterm: GA 28-36 weeks, BW < 2200 g, growth > 10 g/kg/d over the last 5 days.

Term: GA 37-42 weeks, BW > 2500 g, growth > 5 g/kg/d over the last 5 days.

Exclusion criteria

1. Gastro-intestinal pathology;
2. sepsis;
3. syndromes;
4. no informed consent.

Study design

Design

Intervention model: Other

Masking: Open (masking not used)

Control: N/A , unknown

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 15-10-2008

Enrollment: 400
Type: Anticipated

Ethics review

Positive opinion
Date: 16-12-2008
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	NL1517
NTR-old	NTR1588
Other	: 2007-392
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

none