Splanchnic aspartate metabolism in preterm infants

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To quantify splanchnic and whole body aspartate metabolism in premature neonates.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Malabsorption conditions
Study type	Interventional

Summary

ID

NL-OMON30148

Source
ToetsingOnline

Brief title
Splanchnic aspartate metabolism in preterm infants

Condition

- Malabsorption conditions
- Food intolerance syndromes
- Neonatal and perinatal conditions

Synonym
Up take of nutrients in the intestine/ Use of nutrients by the intestineBi

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Hasjinomoto Research fund

Intervention

Keyword: aspartate, metabolism, splanchnic tissue, stable isotopes

Outcome measures

Primary outcome

Plasma and expired air enrichment of IV and IG adminstered labelled aspartate.

For this purpose we will use two different stable isotopes of aspartate.

Secondary outcome

Not applicable

Study description

Background summary

Most premature infants (gestational age < 37 weeks) are in the first postnatal days or weeks fed with parenteral nutrition. Enteral feeding is, depending on the infants clinical condition, commenced after a few days and gradually advanced over time. This is because in the premature newborn the gastro intestinal tract is not fully developed and digestion of nutrients is suboptimal. This increases chances of developing necrotizing enterocolitis (NEC). NEC is an inflammatory bowel disease with a high morbidity/mortality and high incidence in the premature.
However, in these infants we try to establish a growth rate that resembles the intra-uterine growth rate (14-20 gr/kg/day). The intestine plays a key role in this growth because only a well developed gut can absorp the required amount of nutrients. It is known that the portal drained viscera (PDV) (spleen, stomach, intestine and pancreas) although accounting for only 5% of the body weight, are responsible for 35% of energy expenditure. Which substrates are used for this high demand is largely unknown.

Study objective

To quantify splanchnic and whole body aspartate metabolism in premature neonates.

Study design

The design is a single-center intervention non-therapeutic study design. Eight

hours before the start of the study infants will be maintained on regular infant formula, Nenatal. This formula is given in our NICU to infants not receiving mothers milk. Infants usually fed with breastmilk will receive breastmilk again after the study.
At the start of the study infants are infused (IV) for two hours with [13C]natriumbicarbonate (Nabic). This is to determine whole body oxidation. Directly here after [U-13C]aspartate and [2,3,3-D3] aspartate will be infused for 5 hours, one tracer will be given IV and the other IG. On study day 2 the route of administration of the two tracers will be reversed. The simoultaneous infusion of different labeled aspartate will allow us to determine first pass uptake by the splanchnic tissues. Infusion of [U-13C] aspartate on 2 separate days will allow us to calculate the difference in whole body and splanchnic oxidation rate.

Blood samples:
3 samples will be collected:
One sample before to infusion of aspartate (to determine baseline enrichment)
One sample after 4,5 hours of aspartate infusion and one sample at the end of aspartate infusion (after 5 hours)
Expired air collection:
Breath samples will be taken every half hour. During the last hour of Nabic and aspartate infusion samples will be taken every 15 minutes.

Intervention

The Ethical Committee Rotterdam and the CCMO decided that this study should be examined by the CCMO as a non-therapeutical intervention study because the neonate receives formula instead of mother milk during the period of 2 days.

The labelled amino acid is not a substance that will cause a reaction in the body for research purposes. It is a standard part of the enteral feeding, except that it is enriched with a stable isotope 13C, which increases the total enrichment of the C-atoms in the body with 0,001%. The labelled amino acid is not the purpose of the study; the metabolism of nutritional parts is the purpose of this study.

Study burden and risks

On two separate days, three blood samples of 200 ul are requested for this study. This is in total 1,2 ml, which is less than 2% of the blood volume of an infant weighing 1000 grams. If infants have no arterial catheter to withdraw blood samples from the first sample will be combined with the regular morning blood sample collection for clinical purposes. The blood samples at the end of the tracer protocol will then be collected by heel stick. No arterial catheter will be placed for research purposes.
In total 18 breath samples are collected through a 6 Fr gastric tube placed 1

to 1.5 cm into the nasopharynx. This takes approximately a minute per sample and carries no burden to the infant.
Stable isotope techniques have been used for over 20 years in our department for metabolism studies and to the best of our knowledge no adverse effects have ever occurred.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Birth weight between 750 and 1500 grams, admitted to the NICU, at least 1 day on full enteral feeding, clinically stable. Intravenous catheter in situ.

Exclusion criteria

No intravenous catheter in situ, metabolic/congenital disease, abnormal liver or kidney function, clinically instabel, sepsis or NEC. On CPAP or infant flow.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO Date:	12-03-2007
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL13680.000.06