Glutamine-enriched enteral feeding in very low birth weight infants.

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VLBW infants may be susceptible to glutamine depletion as nutritional supply of glutamine is limited in the first weeks after birth. Glutamine depletion has negative effects on functional integrity of the gut and leads to immunosuppression. This...

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

Samenvatting

ID

NL-OMON22969

Bron
NTR

Verkorte titel
GEEF study

Aandoening

Gut adaptation and modulation of the immune response in very low birth weight infants.

Ondersteuning

Primaire sponsor: Prof. W.P.F. Fetter
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Overige ondersteuning: Nutricia Nederland B.V. (Zoetermeer, the Netherlands) provided Nenatal, glutamine and placebo supplementation.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary outcome of the study is time to full enteral feeding, defined as a feeding volume ¡Ý120 mL/kg/day.

Toelichting onderzoek

Achtergrond van het onderzoek

Background:

Enteral feeding of very low birth weight (VLBW) infants is a challenge, since metabolic demands are high and administration of enteral nutrition is limited by immaturity of the gastrointestinal tract. The amino acid glutamine plays an important role in maintaining functional integrity of the gut. In addition, glutamine is utilised at a high rate by cells of the immune system. In critically ill patients, glutamine is considered a conditionally essential amino acid. VLBW infants may be especially susceptible to glutamine depletion as nutritional supply of glutamine is limited in the first weeks after birth. Glutamine depletion has negative effects on functional integrity of the gut and leads to immunosuppression.
This double-blind randomised controlled trial is designed to investigate the effect of glutamine-enriched enteral nutrition on feeding tolerance, infectious morbidity and short-term outcome in VLBW infants. Furthermore, an attempt is made to elucidate the role of glutamine in postnatal adaptation of the gut and modulation of the immune response.

Methods:

VLBW infants (gestational age <32 weeks and/or birth weight <1500 g) are randomly allocated to receive enteral glutamine supplementation (0.3 g/kg/day) or isonitrogenous placebo supplementation between day 3 and 30 of life. Primary outcome is time to full enteral feeding (defined as a feeding volume ¡Ý120 mL/kg/day). Furthermore, incidence of serious infections and short-term outcome are evaluated. The effect of glutamine on postnatal adaptation of the gut is investigated by measuring intestinal permeability and determining faecal microflora. The role of glutamine in modulation of the immune response is investigated by determining plasma Th1/Th2 cytokine concentrations following in vitro whole blood stimulation.

Doel van het onderzoek

VLBW infants may be susceptible to glutamine depletion as nutritional supply of glutamine is

limited in the first weeks after birth. Glutamine depletion has negative effects on functional integrity of the gut and leads to immunosuppression. This double-blind randomised controlled trial is designed to investigate the effect of glutamine-enriched enteral nutrition on feeding tolerance, infectious morbidity and short-term outcome in VLBW infants. Furthermore, an attempt is made to elucidate the role of glutamine in postnatal adaptation of the gut and modulation of the immune response.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Enteral glutamine supplementation in a dose of 0.3 g/kg/day between days 3 and 30 of life versus isonitrogenous placebo supplementation (alanine).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Infants with a gestational age < 32 weeks and/or a birth weight < 1500 grams.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Major chromosomal or congenital anomalies.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	16-09-2001
Aantal proefpersonen:	107
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	12-09-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL169
NTR-old	NTR205
Ander register	: N/A
ISRCTN	ISRCTN73254583

Resultaten

Samenvatting resultaten
1. Glutamine-enriched enteral nutrition in very low birth weight infants. Design of a double-blind randomised controlled trial.
Anemone van den Berg, Ruurd M. van Elburg, Jos W.R. Twisk, Willem P.F. Fetter. Biomed Central Pediatrics 2004;4:17.

2. Glutamine-enriched enteral nutrition in very-low-birth-weight infants and effects on feeding tolerance and infectious morbidity: a randomized controlled trial.
Anemone van den Berg, Ruurd M. van Elburg, Elisabeth A.M. Westerbeek, Jos W.R. Twisk, Willem P.F. Fetter. American Journal of Clinical Nutrition 2005;81:1397-1404.

3. A randomized controlled trial of enteral glutamine supplementation in very low birth weight infants: Plasma amino acid concentrations.
Anemone van den Berg, Ruurd M. van Elburg, Tom Teerlink, Harrie N. Lafeber, Jos W.R. Twisk, Willem P.F. Fetter. Journal of Pediatric Gastroenterology and Nutrition 2005;41:66-71.

4. JPEN J Parenter Enteral Nutr. 2006 Sep-Oct;30(5):408-14.
