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Glutamine-Enriched Enteral Feeding in very low birth weight infants

Submission date	Recruitment status	[_] Prospectively registered
14/07/2004	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/08/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/03/2008	Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR205

Study information

Scientific Title

Acronym
GEEF study

Study objectives
Very Low Birth Weight (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.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The National Central Committee on research involving human subjects and the Medical Ethical Review Board of our hospital approved the study protocol.

Study design
Randomised, placebo controlled, parallel group, double blinded trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Very low birth weight infants

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

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Enteral glutamine supplementation

Primary outcome measure
Time to full enteral feeding, defined as a feeding volume greater than or equal to 120 mL/kg /day.

Secondary outcome measures
1. Feeding tolerance:
1.1. Age at finishing parenteral nutrition
1.2. Days of no enteral feeding during study period
1.3. Necrotising enterocolitis
2. Infectious morbidity:
2.1. Serious infections
2.2. Number of infectious episodes
2.3. Cultured micro-organisms
3. Short-term outcomes:
3.1. Weight z scores at birth, day 30 and at discharge
3.2. Patent ductus arteriosus
3.3. Ventilatory support
3.4. Use of oxygen at postmenstrual age of 36 weeks
3.5. Intraventricular hemorrhage
3.6. Retinopathy of prematurity
3.7. Death
3.8. Age at discharge from NICU and at discharge home
4. Intestinal permeability, determined during the 30 day study period
5. Faecal flora, determined during the 30 day study period
6. Plasma Th1/Th2 cytokine concentrations, determined during the 30 day study period
7. Plasma amino acid profiles, determined during the 30 day study period

Overall study start date
16/09/2001

Completion date
19/10/2004

Eligibility

Key inclusion criteria
1. Infants with a gestational age less than 32 weeks and/or a birth weight less than 1500 g
2. Admitted to the level III Neonatal Intensive Care Unit (NICU) of the Vrije University Medical Centre (VUMC)
3. Written informed consent obtained from all parents

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
107

Key exclusion criteria
1. Major chromosomal or congenital anomalies
2. Death less than 48 hours after birth
3. Transfer to another hospital less than 48 hours after birth
4. Admission from an extraregional hospital

Date of first enrolment
16/09/2001

Date of final enrolment
19/10/2004

Locations

Countries of recruitment
Netherlands

Study participating centre
Vrije University Medical Centre
Amsterdam
Netherlands
1081 HV

Sponsor information

Organisation
Vrije University Medical Centre (VUMC) (The Netherlands)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.vumc.nl/english/

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Industry

Funder Name
Nutricia Nederland B.V. (The Netherlands) - provided neonatal glutamine and placebo supplementation

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	Protocol	01/09/2004		Yes	No
Other publications		01/06/2005		Yes	No
Other publications		01/07/2005		Yes	No
Results article		01/09/2006		Yes	No
Other publications		01/08/2007		Yes	No
Other publications		01/11/2007		Yes	No