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Immune effects of acidic and neutral oligosaccharides in the nutrition of preterm infants: CARROT study

Submission date 08/02/2007	**Recruitment status** No longer recruiting
Registration date 08/02/2007	**Overall study status** Completed
Last Edited 06/05/2014	**Condition category** Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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

NTR884

Study information

Scientific Title

Acronym
CARROT study

Study objectives
Acidic and neutral oligosaccharides supplemented enteral nutrition has a positive effect on infectious morbidity, modulation of the immune response, postnatal adaptation of the gut, feeding tolerance and short-term outcome in Very Low Birth Weight (VLBW) infants.
2006 literature review on http://www.ncbi.nlm.nih.gov/pubmed/16677741.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee VU Medical Centre, 15/02/2007

Study design
Randomised placebo-controlled factorial double-blinded trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Prebiotics, gastrointestinal tract, preterm infants, immune effects

Interventions
Enteral supplementation of acidic and neutral oligosaccharides (20%/80% mixture) in a maximum dose of 1.5 g/kg/day during the first month of life.

Intervention Type
Supplement

Phase

Not Specified

Drug/device/biological/vaccine name(s)
Enteral supplementation of acidic and neutral oligosaccharides

Primary outcome measure
1. The effect of acidic and neutral oligosaccharides supplemented enteral feeding on infectious morbidity
2. The incidence of serious infections, using the previously described criteria for serious infections in preterm infants at high risk for serious infections, are prospectively documented from birth until discharge home

Secondary outcome measures
The effect of acidic and neutral oligosaccharides supplemented enteral nutrition on feeding tolerance, short-term outcome, postnatal adaptation of the gut and modulation of the immune response

Overall study start date
01/04/2007

Completion date
01/04/2010

Eligibility

Key inclusion criteria
Infants born with a gestational age of less than 32 weeks and/or a birthweight of less than 1500g

Participant type(s)
Patient

Age group
Neonate

Sex
Not Specified

Target number of participants
108

Key exclusion criteria
1. Severe congenital disorders, like cardiac disorders, syndromal disorders, immunodeficiency disorders
2. Congenital disorders of the gastrointestinal tract

Date of first enrolment
01/04/2007

Date of final enrolment
01/04/2010

Locations

Countries of recruitment
Netherlands

Study participating centre
VU University Medical Centre
Amsterdam
Netherlands
1007 MB

Sponsor information

Organisation
VU University Medical Centre (VUMC) (Netherlands)

Sponsor details
Department of Paediatrics and Neonatology
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w.fetter@vumc.nl

Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Industry

Funder Name
Numico Research B.V. (Netherlands)

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	23/10/2008		Yes	No
Results article	results	01/03/2010		Yes	No
Results article	external supplementation results	01/01/2011		Yes	No
Results article	results	08/08/2013		Yes	No