

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	<input checked="" type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
Registration date 08/02/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 06/05/2014	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> 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

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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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