Dolphin CONTINUE – Concept of Nutrition To Improve NeUrodevelopment in Early life

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Encephalopathies
Study type	Interventional

Summary

ID

NL-OMON23524

Source
NTR

Brief title
Dolphin CONTINUE

Condition

- Encephalopathies

Health condition

Encephalopathy of prematurity

Research involving
Human

Sponsors and support

Primary sponsor: University Medical Center Utrecht, Department of

	Neonatology, Division Woman and Baby, Lundlaan 6, 3584 EA Utrecht
Secondary sponsors:	Health Holland / TKI; , Faculty of Social Behavioral Sciences, Utrecht University;, Danone Nutricia Research; Dep. of Neonatology, Dep. of Neonatology, UMC Utrecht
Source(s) of monetary or material Support:	Health Holland / TKI Faculty of Social and Behavioral Sciences, Utrecht University Danone Nutricia Research Dep. of Neonatology, UMC Utrecht

Intervention

- Food (substances)

Explanation

Outcome measures

Primary outcome

The primary outcome parameter in this study is white matter microstructural integrity, specifically: DTI-derived FA of white matter tracts at a corrected age of 3 months (Time-point 5), analyzed using TBSS.

Secondary outcome

The secondary outcome parameter will be neurodevelopmental follow-up outcomes, specifically: cognitive and motor scores on the Bayley Scales of Infant and Toddler Development-III (BSID-III) at the corrected age of 2 years (Time-point 9). Additional secondary outcomes include cognitive and language development as measured by standardized questionnaires including the N-Communicative Development Inventories, Ages & Stages Questionnaire (Time-point 7 & 9), and Parent Report of Children's Abilities-Revised (Time-point 9). Furthermore, other measures on brain anatomy, including brain tissue volumes, cortical morphology, and other DTI parameters (radial, axial, and mean diffusivity) will be derived from T1-, T2- and diffusion weighted MRI scans (Time-point 5).

Study description

Background summary

Early neonatal events affecting brain development can have long-lasting consequences for motor and cognitive outcome. At present, medical treatment options for brain-injured infants are limited. Optimizing nutrition during the first years after birth of rapid brain development

may provide a means to improve neurodevelopment.

Study objective

The main objective is to study the effect of a nutritional intervention on white matter integrity at the corrected age of three months in infants born at a gestational age <30+0 weeks. Secondary objectives of the study are to determine the effect of the nutritional intervention on neurodevelopmental outcomes at 12 to 24 months corrected age, safety and other MRI parameters.

Study design

A total of 130 infants will be randomized (1:1) to receive test or control product at home until 12 months corrected age in an exploratory randomized, placebo-controlled, double blind, parallel group, multi-center, single country trial. The follow-up period without study product starts after finishing the nutritional intervention around 12 months corrected age and continues until 24 months corrected age.

Intervention

The investigational supplement is a nutrient blend containing a.o. long-chain polyunsaturated fatty acids (LCPUFAs), choline, Uridine-5’-Monophosphate (UMP), and cytidine monophosphate (CMP).

Contacts

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Eligibility criteria

Age

Premature newborns (<37 weeks pregnancy)
Premature newborns (<37 weeks pregnancy)

Inclusion criteria

1. Written informed consent of custodial caregivers

2. Preterm born infants born at a gestational age <30+0 weeks

Exclusion criteria

1. Any relevant proven or suspected chromosomal anomaly, metabolic disorder or genetic syndrome

2. Presence of a congenital central nervous system infection or malformation (note that infants with acquired brain injury such as hemorrhages, white matter injury or stroke are eligible for inclusion)

3. Presence of any congenital gastrointestinal malformation (infants with a stoma following surgery are not necessarily excluded, at the discretion of the attending physician)

4. No realistic prospect of survival at the discretion of the attending physician

5. Expected or foreseen inability of the subject's custodial caregivers to adhere to protocol instructions

6. (Previous) participation in other nutritional intervention studies involving investigational or marketed nutritional products concomitantly or within three weeks prior to start study product intake, that could impact on the main outcome parameters and/or subject safety (at the discretion of the coordinating investigator)

7. Infants who have or are suspected of having a cow's milk allergy and/or have already started with extensively hydrolyzed milk

8. Infants who have or are suspected of having egg allergy (or products thereof), fish oil allergy (or products thereof) and/or lactose intolerance as these are present in the study product

9. Withdrawal of informed consent by custodial caregivers

10. Infants who are not fully enterally fed and/or unlikely to start the nutritional intervention at home at 40-43 weeks post-menstrual age

11. Infants who are expected to be unable to undergo MRI under sedation at three months of corrected age.

Study design

Design

Study phase:	N/A
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Supportive care

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-05-2022
Enrollment:	130
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Approved WMO

Date:	28-10-2021
Application type:	First submission
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

ID: 56181
Bron: ToetsingOnline

Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9814
Other	METC UMCU : METC 21-504/M
CCMO	NL72700.041.21
OMON	NL-OMON56181

Study results