Effect of early fatty acid status on neurodevelopmental outcome at 9 years.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21520

Source NTR

Brief title LCP project

Health condition

typically developing children

Sponsors and support

Source(s) of monetary or material Support: Numico Research B.V.

EUs Sixth Framework programme for Research and Technological Development: part of Integrated Project entitled EARNEST (EARly Nutrition programming – long term follow up of Efficacy and Safety Trials and integrated epidemiological, genetic, animal, consumer and economic research)

Intervention

Outcome measures

Primary outcome

Neuromotor condition at 9 years.

Secondary outcome

Cognitive function at 9 years:

- 1. Attention and executive functions;
- 2. Language;
- 3. Memory and learning;
- 4. Behavioural problems.

Study description

Background summary

The central nervous system contains a high level of long-chain polyunsaturated fatty acids (LCPUFAs). LCPUFAs accrue rapidly in the grey matter of the brain during development, in particular during the last trimester of gestation and the first weeks after term age. LCPUFA status during early infancy and LCPUFA supplementation of formula feeding has a beneficial effect on visual and neuromotor development in early infancy.

But it is debated whether LCPUFAs can affect neurodevelopmental outcome of term infants beyond the age of one year. Possibly, LCPUFAs do not affect global measures of long term neurodevelopmental outcome, but only specific ones, such as neural functions which heavily rely on cortical-subcortical circuitries.

The present project aims at evaluating the effect of

a) neonatal fatty acid status (based on fatty acid composition of umbilical vessels) and b) LCPUFA supplementation of formula feeding during the first two postnatal months on specific parameters of neurodevelopmental outcome, which are dependent on the integrity of (sub)cortical pathways, at the age of nine years in a group of 457 healthy term infants. The children of the project participated in a prospective double-blind randomised control study on the effect of LCPUFA supplementation for the duration of two months on neurodevelopmental outcome till 18 months of age (attrition 8%). At birth the children were allocated into three groups, a control formula (CF) group (n=162), a LCPUFA-supplemented formula (LF) group (n=139) and a breast-fed (BF) group (n=156). The latter served as a reference.

In 310 children fatty acid status could be determined in umbilical vessels.

Evaluation at 9 years will consist of a standardized neurological examination according to Touwen aiming at the detection of minor neurological dysfunction. In addition, we will evaluate frontal lobe function with Luria's Flat-Fist-Edge test, mental processing with parts of the NEPSY battery, such as the tests evaluating attention and executive functions and those assessing memory and learning, and behavioural problems, including attention problems, with the help of standardized questionnaires for parent and teachers.

The data will not only be analysed by means of univariate tests but also with multivariate statistics in order to take into account the effect of confounders such as social class, parental education and the child's gender.

Study objective

 Postnatal supplementation of infant formula with long-chain polyunsaturated fatty acids (LCPUFA) improves neurodevelopmental outcome at 9 years in healthy full-term infants;
Neonatal fatty acid status affects neurodevelopmental outcome at 9 years in healthy full-term infants.

Intervention

Standard infant formula enriched with 0.45 % AA and 0.30 % DHA.

Contacts

Public

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Eligibility criteria

Inclusion criteria

Healthy term infants.

Exclusion criteria

- 1. A congenital disorder interfering with adequate functioning in daily life;
- 2. Children from multiple births;

3. Children whose mother did not master the Dutch language or suffered from significant illness or disability;

- 4. Adopted and fostered children;
- 5. Formula-fed infants who had received human milk for more than 5 days.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

Recruitment

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NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-04-2005
Enrollment:	457
Туре:	Anticipated

Ethics review

Positive opinion	
Date:	12-09-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL326
NTR-old	NTR364
Other	: N/A
ISRCTN	ISRCTN52788665

Study results

Summary results

N/A