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

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1. Postnatal supplementation of infant formula with long-chain polyunsaturated fatty acids (LCPUFA) improves neurodevelopmental outcome at 9 years in healthy full-term infants; 2. Neonatal fatty acid status affects neurodevelopmental outcome at 9...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21520

Bron NTR

Verkorte titel LCP project

Aandoening

typically developing children

Ondersteuning

Overige ondersteuning: 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)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1 - Effect of early fatty acid status on neurodevelopmental outcome at 9 years. 6-05-2025

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

 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.

2 - Effect of early fatty acid status on neurodevelopmental outcome at 9 years. 6-05-2025

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

University Medical Center Groningen (UMCG)
 Beatrix Children's Hospital
Developmental Neurology P.O. Box 30.001 M. Hadders-Algra Hanzeplein 1 Groningen 9700 RB The Netherlands +31 (0)50 3614252

Wetenschappelijk

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 Beatrix Children's Hospital
Developmental Neurology P.O. Box 30.001 M. Hadders-Algra Hanzeplein 1 Groningen 9700 RB The Netherlands +31 (0)50 3614252

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Healthy term infants.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 1. A congenital disorder interfering with adequate functioning in daily life;
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- 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.

Onderzoeksopzet

Opzet

nterventie onderzoek
Parallel
)pen / niet geblindeerd
Geneesmiddel

Deelname

Nederland		
Status:	Werving gestart	
(Verwachte) startdatum:	01-04-2005	
Aantal proefpersonen:	457	
Туре:	Verwachte startdatum	

Ethische beoordeling

Positief advies	
Datum:	12-09-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten N/A