

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

Submission date 19/12/2005	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 19/12/2005	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 18/02/2021	Condition category Mental and Behavioural Disorders	☐ 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

Protocol serial number
NTR364

Study information

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

Acronym

LCP project

Study objectives

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 years in healthy full-term infants

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from local medical ethics committee

Primary study design

Interventional

Study design

Randomised open label active controlled parallel group trial

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Developmental disorder

Interventions

Three groups:

1. Control formula (CF) group (n = 162),
2. LCPUFA-supplemented formula (LF) group (n = 139)
3. Breast-fed (BF) group (n = 156).

LCPUFA-supplemented formula (LF) group: standard infant formula enriched with 0.45% arachidonic acid (AA) and 0.30% docosahexaenoic acid (DHA).

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Neuromotor condition at 9 years

Key secondary outcome(s)

Cognitive function at 9 years:

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

Completion date

31/03/2010

Eligibility

Key inclusion criteria

Healthy term infants

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Sex

All

Total final enrolment

229

Key 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

Date of first enrolment

01/04/2005

Date of final enrolment

31/03/2010

Locations

Countries of recruitment

Netherlands

Study participating centre

University Medical Center Groningen

Groningen

Netherlands

9700 RB

Sponsor information

Organisation

University Medical Centre Groningen (UMCG) (Netherlands)

ROR

<https://ror.org/03cv38k47>

Funder(s)

Funder type

Industry

Funder Name

Numico Research B.V. (Netherlands)

Results and Publications

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?
Results article	results	01/09/2016	18/02/2021	Yes	No