ISRCTN52788665 https://doi.org/10.1186/ISRCTN52788665

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

Submission date	Recruitment status
19/12/2005	No longer recruiting
Registration date	**Overall study status**
19/12/2005	Completed
Last Edited	**Condition category**
18/02/2021	Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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
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

Study design
Randomised open label active controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet

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 measure
Neuromotor condition at 9 years

Secondary outcome measures
Cognitive function at 9 years:
1. Attention and executive functions
2. Language
3. Memory and learning
4. Behavioural problems

Overall study start date
01/04/2005

Completion date
31/03/2010

Eligibility

Key inclusion criteria
Healthy term infants

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
457

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)

Sponsor details
Beatrix Children's Hospital
P.O. Box 30001
Groningen
Netherlands
9700 RB

Sponsor type
Hospital/treatment centre

Website
http://www.umcg.nl/azg/nl/english/azg/

ROR
https://ror.org/03cv38k47

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