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Friso MUM, the activity of a health supplement during pregnancy and lactation

Submission date	Recruitment status
19/12/2005	No longer recruiting
Registration date	**Overall study status**
19/12/2005	Completed
Last Edited	**Condition category**
07/01/2021	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

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effect of high docosahexaenoic acid (DHA)-fish oil and arachidonic acid (AA) suppletion during pregnancy and lactation on long-chain polyunsaturated fatty acids (LCP) status of mother and child and on the neurological development of the baby

Acronym
MUM

Study objectives
Docosahexaenoic acid (DHA) and arachidonic acid (AA) during pregnancy shall lead to a better neurological development of the baby and possibly to better mood, cognitive functioning and sleeping rhythm of the mother.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local medical ethics committee

Study design
Randomised double-blind, placebo controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Developmental disorder

Interventions
Everybody receives a multivitamin supplement (designed for pregnant women). As well as this we compare placebo versus DHA versus DHA/AA.

Intervention Type
Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)
Docosahexaenoic acid (DHA), arachidonic acid (AA)

Primary outcome measure
Neurological development of the baby (Neurological Optimality Score and General Movements)

Secondary outcome measures
1. Mood, cognitive functioning and sleeping rhythm of the mother
2. LCP status in red blood cells of mother (16th and 36th week) and child (12 weeks after birth), umbilical cord, breast milk (2 and 12 weeks after birth)

Overall study start date
01/11/2004

Completion date
01/10/2007

Eligibility

Key inclusion criteria
1. Apparently healthy pregnant women
2. Para 0 or 1
3. Inclusion should take place prior to the 16th week of pregnancy

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
300

Total final enrolment
119

Key exclusion criteria
1. Hyperemesis Gravidarum
2. Vegetarian or vegan
3. Pregnant with twins
4. Diabetes Mellitus type 1
5. Usage of health supplements with fatty acids, tryptophan or melatonin

Date of first enrolment
01/11/2004

Date of final enrolment
01/10/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Center Groningen
Groningen
Netherlands
9700 RB

Sponsor information

Organisation
Friesland Foods (The Netherlands)

Sponsor details
PO Box 159
Ede
Netherlands
6710 BD

Sponsor type
Industry

ROR
https://ror.org/025mtxh67

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

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	01/02/2009	07/01/2021	Yes	No