

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

Submission date 19/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 19/12/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 07/01/2021	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> 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
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