ISRCTN03848493 https://doi.org/10.1186/ISRCTN03848493

DHA for PREGnant women: is the current recommendation appropriate for women with very low intake and status?

Submission date
16/05/2014

Recruitment status
No longer recruiting

Registration date
20/08/2014

Overall study status
Completed

Last Edited
01/04/2016

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
It is vital that pregnant women eat a healthy diet that contains essential nutrients such as folic acid and calcium. It is widely acknowledged that another nutrient, DHA omega 3 (docosahexaenoic acid) is also very important; it is needed for the normal development of the babies brain, eyes and nervous system. Babies in the womb are not really able to produce DHA and therefore must get it from their mother though the placenta. DHA is also considered to have health benefits for the mother. Alpha-linolenic acid (ALA) omega -3 can be converted into DHA. The body cannot make ALA so this has to be eaten as part of a healthy diet. ALA can be found is small amounts in most vegetable oils and in greater amounts in flaxseed, soybeans, walnuts and olive oil. DHA is found in significant amounts in sea food. However, many people do not eat enough DHA and/or ALA rich foods, and that includes those from richer countries. It has been recommended that pregnant women and nursing mothers eat 300 mg/d and at least 200mg /d of DHA every day, but these are only estimates. In an earlier study, we compared the amount of DHA in British pregnant women and their newborn babies (neonates) with those from Sudan. It was found that the level of DHA in Sudanese mothers and their newborn babies were considerably lower than for those from Britain (50% lower in the blood plasma and 85% lower in breast milk). Here, we want to know whether giving the Sudanese mothers 200 or even 300 mg /d DHA supplements would increase DHA levels in the blood plasma and breast milk to match the levels found in British women who dont take the supplement. The aims of the study are: to find out the amount of DHA supplement needed to increase the levels in Sudanese expectant and nursing mothers to those commonly observed in British women; find out whether DHA supplementation before birth is enough to raise the amount of DHA in breast milk to that found in women who receive the supplementation before and after birth; find out how DHA supplementation can affect growth on the unborn baby, the likelihood of premature birth, the weight of the baby at birth and also the size of its head and length.

Who can participate?
Healthy pregnant women expecting one child.

What does the study involve?
Participants are randomly allocated into one of three groups. Those in group 1 are asked to take 575 mg omega 3 FA (contains 322.5 mg DHA & 47.2 mg EPA). Those in group B take 1,725 mg omega 3 FA (contains 967.7 mg DHA & 141.5 mg EPA). Those in group 3 take a placebo (dummy) pill. Blood will be collected at the start of the trial, at time of delivery (from both the mother and cord) and then at 6 weeks after birth. Placenta tissue will be obtained at delivery. Participants will be asked to provide a sample of breast milk 6 weeks after the birth of their baby.

What are the possible benefits and risks of participating?
DHA supplement during pregnancy is known to be beneficial for the eye and brain development of the neonates. There is no risk of participating.

Where is the study run from?
The study has been set up by the Lipidomics and Nutrition Research Centre, Faculty of Life Sciences and Computing, London Metropolitan University (UK) in collaboration with the University of Khartoum Hospital, Khartoum (Sudan).

When is study starting and how long is it expected to run for?
September 2014 to February 2017

Who is funding the study?
Lipidomics and Nutrition Research Centre (UK)
University of Khartoum Hospital (Sudan)
Efamol Limited (UK)

Who is the main contact?
Professor Kebreab Ghebremeskel
k.ghebremeskel@londonmet.ac.uk OR keb@kebgm.demon.co.uk

Contact information

Type(s)
Scientific

Contact name
Prof Kebreab Ghebremeskel

Contact details
Lipidomics and Nutrition Research Centre
Faculty of Life Sciences and Computing, London Metropolitan University
166-220 Holloway Road
London
United Kingdom
N7 8DB
-
k.ghebremeskel@londonmet.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
DHA4PREG

Study information

Scientific Title
DHA supplementation to improve maternal, foetal and infant outcomes: is the current recommendation appropriate for women with very low intake and status?

Acronym
DHA4PREG

Study objectives
1. Supplemented pregnant and lactating Sudanese women and their unsupplemented counterparts have comparable blood and breast milk DHA concentrations
2. Sudanese women who received antenatal supplementation and those supplemented during pregnancy and lactation periods have similar levels of breast milk DHA at postnatal week 6
3. DHA supplementation will not have significant effects on foetal growth, premature delivery, gestation week at delivery and birth anthropometry (birth weight, head circumference and length)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee of the Faculty of Medicine, University of Khartoum, Sudan, 09/09/2014,
ref: FM/DO/EC

Study design
Double-blind placebo-controlled randomised intervention trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Pregnancy

Interventions
Participants will be asked to take one of three supplements:
1. 575 mg omega 3 FA (contains 322.5 mg DHA & 47.2 mg EPA)
2. 1,725 mg omega 3 FA (contains 967.7 mg DHA & 141.5 mg EPA)
3. Placebo (contains no omega-3 fatty acids)

Intervention Type
Supplement

Primary outcome measure
DHA level in maternal and cord blood at delivery

Secondary outcome measures
1. DHA level in breast milk at postnatal week 6
2. Anthropometric measurement of babies at birth and postnatal week 6

Overall study start date
01/09/2014

Completion date
28/02/2017

Eligibility

Key inclusion criteria
Healthy women with singleton pregnancy

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
180

Key exclusion criteria
1. Pre-existing chronic medical conditions such as diabetes, high blood pressure, congenital heart disease, kidney disease, very preterm delivery

2. Sickle cell disease or hemoglobinopathies
3. History of pre-eclampsia, stillbirth or foetal death, major foetal anomaly
4. Smoking or other illegal-substance abuse

Date of first enrolment
01/09/2014

Date of final enrolment
28/02/2017

Locations

Countries of recruitment
England

Sudan

United Kingdom

Study participating centre
London Metropolitan University
London
United Kingdom
N7 8DB

Sponsor information

Organisation
Faculty of Life Sciences and Computing, London Metropolitan University (UK)

Sponsor details
166-220 Holloway Road
London
England
United Kingdom
N7 8DB
-
d.palmer-brown@londonmet.ac.uk

Sponsor type
University/education

Website
http://www.londonmet.ac.uk

ROR
https://ror.org/00ae33288

Funder(s)

Funder type
University/education

Funder Name
Lipidomics and Nutrition Research Centre, London Metropolitan University, London (UK)

Funder Name
University of Khartoum Hospital (Sudan)

Funder Name
Efamol Limited (UK)

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