

Maternal Fish Oil Supplementation Study in high risk pregnancies

Submission date 13/06/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 02/09/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 26/08/2016	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The aim of this study is to determine whether providing women with high-risk pregnancies (i.e., with diabetes or at risk of low birth weight) with fish oil supplementation affects the magnetic resonance imaging (MRI) brain findings and development of their infants.

Who can participate?

Pregnant women with high-risk pregnancies with a known or recent diagnosis of diabetes or those at risk of delivering a low birth weight baby.

What does the study involve?

Participants will be randomly allocated to one of two groups. One group will receive fish oil supplements and the other group will receive olive oil, which is known to have health benefits from reports on the Mediterranean diet and longevity. Both groups will receive their routine antenatal care. The mothers will provide blood samples for testing of lipid (fat) profiles and iron status, and will complete questionnaires. The infants born to the mothers in the study groups will also be followed up for assessments including weight, length and head circumference. Cord blood will be taken at delivery to determine their blood lipid levels and stool samples will be obtained. The infants will undergo a brain MRI scan. Visual attention will be determined at each visit and a formal visual test will be undertaken at 9 months of age

What are the possible benefits and risks of participating?

Fish oil supplementation may result in improvement of the lipid profile of mothers and their babies.

Where is the study run from?

Imperial College (UK).

When is study starting and how long is it expected to run for?

The study will run from April 2010 to March 2013.

Who is funding the study?

Mother and Child Foundation (UK).

Who is the main contact?
Dr Enitan Ogundipe
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Maternal Fish Oil Supplementation in high risk pregnancies and the effect on the infants' brain MRI findings and neurobehavioural outcomes

Acronym
FOSS study

Study objectives
To determine whether maternal fish oil supplementation in women with high risk pregnancies, i. e. diabetes and risk of low birthweight affects the MRI brain findings and developmental outcomes of their infants

We postulate that high risk mothers and their fetuses will have lower docosahexaenoic acid (DHA) (in fish oil) levels than controls. Maternal supplementation with fish oil will result in improvement of the lipid profile of mothers and their fetuses. The un-supplemented group of infants will have lower grey matter and total brain volumes on MRI scans which will correlate to the neuro-developmental test scores.

Aims:
To determine whether lipid profiles and markers of oxidative stress differ between pregnant

mothers supplemented with fish oils and those who are not, and if there is a relationship to their infants Brain MRI findings.

2. To determine whether supplementing pregnant and lactating high risk mothers with omega 3 affects the maternal psycho-behavioural outcomes

3. To determine whether supplementing pregnant mothers affects the infant postnatal morbidity, stool microflora, growth and neuro-developmental outcome.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Double blind randomised placebo controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Maternal diabetes mellitus, pre-eclampsia, low birthweight

Interventions

1. Fish oil supplements or placebo

2. MRI infant brain scan

3. Neuro-behavioural assessments of mother and infants

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Infants MRI brain scan findings

2. Maternal lipid profile

Key secondary outcome(s)

1. Infant developmental outcomes

2. Maternal neurobehavioural outcomes

Completion date

31/03/2013

Eligibility

Key inclusion criteria

All pregnant women in high risk pregnancies with known or recent diagnosis of diabetes mellitus or those at risk of delivering a low birthweight baby cared for at the Chelsea & Westminster Hospital, London United Kingdom

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Fish allergy
2. Inability to speak english and refusal to use an interpreter
3. Non-resident in London
4. Unable to attend the follow up appointments

Date of first enrolment

01/04/2010

Date of final enrolment

31/03/2013

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Neonatal Unit, Chelsea & Westminster Hospital

London

United Kingdom

SW10 9NH

Sponsor information

Organisation

Mother and Child Foundation (UK)

ROR

<https://ror.org/030ybgp98>

Funder(s)

Funder type

Charity

Funder Name

Mother and Child Foundation (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration