

# Maternal Fish Oil Supplementation Study in high risk pregnancies

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 02/09/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 26/08/2016	<b>Condition category</b> 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**  
Dr Enitan Ogundipe

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**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**

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 measure**

1. Infants MRI brain scan findings
2. Maternal lipid profile

**Secondary outcome measures**

1. Infant developmental outcomes
2. Maternal neurobehavioural outcomes

**Overall study start date**

01/04/2010

**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

**Age group**

Adult

**Sex**

Female

**Target number of participants**

300 pregnant women and their infants

**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**

England

United Kingdom

**Study participating centre**

**Neonatal Unit, Chelsea & Westminster Hospital**

London

United Kingdom

SW10 9NH

## Sponsor information

**Organisation**

Mother and Child Foundation (UK)

**Sponsor details**

36 Regents Park Road

London

United Kingdom

NW1 7SX

**Sponsor type**

Charity

**Website**

<http://www.mother-and-child.org>

**ROR**

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

## Funder(s)

**Funder type**

Charity

**Funder Name**

Mother and Child Foundation (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