

Dietary fish oil supplementation in pregnant women with diabetes

Submission date 30/07/2010	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 30/07/2010	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 15/10/2015	Condition category Nutritional, Metabolic, Endocrine	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Previous studies suggest that for women with pre-existing diabetes (type 2 diabetes) or who develop diabetes during pregnancy (gestational diabetes), or have insufficient amounts of certain nutrients when pregnant, their child has higher risk of becoming overweight and insulin resistant (which means your body does not control blood sugar efficiently). Moreover, children born to diabetic women are more vulnerable to develop diabetes and high blood pressure in adulthood. In our previous study, we have found that diabetic women and their newborn babies have lower levels of certain nutrients (omega-3 and omega-6 fatty acids) in the blood. These nutrients are found in various foods, for example you can find omega-3 in fish or seafood (mussel, crab, cockles, prawn, etc.) and omega-6 in eggs, offal, red meat or some fish. Evidence suggests that people with lower amounts of omega-3 and omega-6 fatty acids in their body may not be able to control blood sugar efficiently. Also, diabetics have lower amounts of these nutrients in their blood. The purpose of the study is to investigate if supplementing omega-3 and omega-6 fatty acids during pregnancy can improve women's health as well as their babies.

Who can participate?

Pregnant women with type 2 diabetes or gestational diabetes, without any other clinical condition.

What does the study involve?

Women will be randomly allocated to receive either capsules containing omega-3 and omega-6 fatty acids, or placebo (dummy) capsules containing sunflower oil.

What are the possible benefits and risks of participating?

The benefit of taking omega-3 and/or omega-6 fatty acids in diabetic pregnancy is not yet known. However, the information we get from this study may help us to treat future patients with diabetes and their children better. Omega-3 fatty acids are nutrients widely present in fish and other marine food and do not present any risk.

Where is the study run from?

Recruitment of women, follow-up and clinical assessment will be conducted at the Newham University Hospital NHS Trust (UK).

When is the study starting and how long is it expected to run for?
The study started in June 2007 and expected to run for 5 years.

Who is funding the study?
FP6 Marie Curie Actions-Transfer of Knowledge (Contract no. MTKD-CT-2005-029914)
The Foyle Foundation
The Mother and Child Foundation
The Letten Foundation
Vifor Pharma
Sir Halley Stewart Trust
Newham University Hospital NHS Trust
Diabetes Research Network (North East London Diabetes Local Research Network)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
UKCRN ID 3772

Study information

Scientific Title
Dietary omega-3 and omega-6 fatty acids supplementation in pregnant women with diabetes: a randomised, double-blind, placebo-controlled trial

Acronym
FOSIP

Study objectives

Current hypothesis as of 14/02/2012:

Supplementation with DHA and AA during pregnancy will correct red cell membrane abnormality of the two fatty acids in diabetic women and neonates.

Previous hypothesis:

The study is a placebo-controlled, double-blind, randomised supplementation trial. A cohort of pregnant women with diabetes, type 1 diabetes mellitus (T1DM; n = 80), type 2 diabetes mellitus (T2DM; n = 80), gestational (n = 80), healthy controls (n = 80) will be recruited from Newham University NHS Trust.

On 14/02/2012 the following changes were made to the trial record:

1. The public title was changed from 'Dietary fish oil supplementation to improve maternal and foetal nutritional status in diabetic pregnancy' to 'Dietary Fish Oil Supplementation In Pregnant women with diabetes'.
2. The acronym was changed from 'Dietary fish oil supplementation in diabetic pregnancy DRN064' to 'FOSIP'.
3. The study design was changed from 'Single centre randomised interventional treatment trial' to 'Randomised double-blind placebo-controlled trial'.
4. The target number of participants was changed from 245 to 320.
5. The overall trial start date was changed from 26/10/2007 to 01/06/2007.
6. The overall trial end date was changed from 01/05/2012 to 01/06/2012.

On 21/06/2013 the sources of funding field was updated; the previous sources of funding were European Commission (Belgium) - The Sixth Framework Programme (FP6) and The Mother and Child Foundation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. East London & The City HA Local Research Ethics Committee 3, REC ref: 06/Q0605/89
2. MREC, 18/12/2006, ref: 06/Q0605/89

Primary study design

Interventional

Study design

Randomised double-blind placebo-controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Diabetic pregnancy

Interventions

Current interventions as of 14/02/2012:

Subsequent to recruitment the diabetics (type 2 and gestational) and healthy non-diabetic controls will be randomly assigned to the treatment or the placebo group. The treatment groups will receive two gelatine capsules a day providing 600 mg DHA and 17 mg AA until delivery. The

capsule also contains 2.8 mg of vitamin E per gram polyunsaturated fatty acids to prevent oxidation. The control (placebo) groups will receive one gelatine capsule per day containing an inert placebo (high oleic acid sunflower oil) and vitamin E per day until delivery.

Previous interventions:

Treatment (600 mg docosahexaenoic acid [DHA] and 200 mg arachidonic acid [AA]) until delivery. The treatment capsule also contains 10 µg of vitamin E per gram polyunsaturated fatty acids to prevent oxidation.

Follow-up length: 24 months

Study entry: registration and one or more randomisations

Intervention Type

Supplement

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Fish oil supplement

Primary outcome(s)

Current primary outcome measure(s) as of 14/02/2012

1. Maternal and foetal (cord) membrane lipid fatty acid levels at delivery

Previous primary outcome measure(s)

1. Corrects the membrane lipid abnormality in diabetic mothers and their neonates

Key secondary outcome(s)

Current secondary outcome measure(s) as of 14/02/2012

1. Foetal body fat distribution

2. Placental lipid fatty acids composition and expression of placental fatty acid binding and transporter proteins

Previous secondary outcome measure(s)

1. Enhances insulin sensitivity in women with gestational diabetes

2. Upregulates placental fatty acid-binding and -transporter proteins and their mRNAs

Completion date

01/06/2012

Eligibility

Key inclusion criteria

Current inclusion criteria as of 14/02/2012:

1. Pregnant women aged 17-45 years old without any medical condition

2. Pregnant women aged 17-45 years old with diabetes (type 2 diabetes or gestational diabetes)

Previous inclusion criteria:

1. Pregnant women with or without diabetes (type 1, type 2, gestational diabetes)
2. Eligible age: 17 - 40 years
3. Control subjects without diabetes

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

Current exclusion criteria as of 21/06/2013:

1. Pregnancy with more than one foetus
2. Known major foetal anomaly
3. Current or planned corticosteroid therapy
4. Asthma requiring medication
5. Current or planned beta-adrenergic therapy
6. Chronic medical conditions such as HIV/AIDS, kidney disease, or congenital heart disease
7. Hematologic or autoimmune disease such as sickle cell disease, other hemoglobinopathies, lupus, or antiphospholipid syndrome
8. Previous or planned tocolytic therapy to induce labour or increase contraction strength

Previous exclusion criteria until 21/06/2013:

1. Smokers
2. History of stillbirth or foetal death
3. Pregnancy with more than one foetus
4. Known major foetal anomaly
5. Current or planned corticosteroid therapy
6. Asthma requiring medication
7. Current or planned beta-adrenergic therapy
8. Chronic hypertension requiring medication within 6 months of or during pregnancy
9. Chronic medical conditions such as HIV/AIDS, kidney disease, or congenital heart disease
10. Hematologic or autoimmune disease such as sickle cell disease, other hemoglobinopathies, lupus, or antiphospholipid syndrome
11. Maternal or foetal conditions likely to require preterm delivery, such as pre-eclampsia, preterm labour, or intrauterine growth retardation
12. Previous or planned tocolytic therapy to induce labour or increase contraction strength

Previous exclusion criteria until 14/02/2012:

1. Smokers
2. History of stillbirth or foetal death
3. Pregnancy with more than one foetus
4. Known major foetal anomaly

5. Asthma requiring medication
6. Current or planned beta-adrenergic therapy
7. Chronic hypertension requiring medication within 6 months of, or during, pregnancy
8. Chronic medical conditions such as HIV/AIDS, kidney disease or congenital heart disease
9. Haematologic or autoimmune disease such as sickle cell disease
10. Other haemoglobinopathies
11. Lupus or antiphospholipid syndrome
12. Maternal or foetal conditions likely to require preterm delivery, such as pre-eclampsia, or intrauterine growth retardation

Date of first enrolment

01/06/2007

Date of final enrolment

01/06/2012

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

London Metropolitan University

London

United Kingdom

N7 8DB

Sponsor information

Organisation

Newham University Hospital NHS Trust (UK)

ROR

<https://ror.org/00b31g692>

Funder(s)

Funder type

Government

Funder Name

FP6 Marie Curie Actions-Transfer of Knowledge (Contract no. MTKD-CT-2005-029914)

Funder Name

Foyle Foundation

Alternative Name(s)

The Foyle Foundation, FF

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Funder Name

Letten Foundation

Funder Name

Vifor Pharma

Alternative Name(s)

Vifor Pharma Management Ltd., Vifor Pharma Management AG, Vifor Pharma Management SA, Vifor Pharma Ltd.

Funding Body Type

Private sector organisation

Funding Body Subtype

For-profit companies (industry)

Location

Switzerland

Funder Name

Sir Halley Stewart Trust

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Funder Name

Newham University Hospital NHS Trust

Funder Name

Diabetes Research Network (North East London Diabetes Local Research Network)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary****Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2014		Yes	No
Results article	results	01/06/2016		Yes	No