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Dietary fish oil supplementation in pregnant women with diabetes

Submission date
30/07/2010

Recruitment status
No longer recruiting

Registration date
30/07/2010

Overall study status
Completed

Last Edited
15/10/2015

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised double-blind 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
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 measure
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

Secondary outcome measures
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

Overall study start date
01/06/2007

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

Age group
Adult

Sex
Female

Target number of participants
320

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
England

United Kingdom

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

Sponsor information

Organisation
Newham University Hospital NHS Trust (UK)

Sponsor details
Glen Road
Plaistow
England
United Kingdom
E13 8SL

Sponsor type
Hospital/treatment centre

Website
http://www.newhamuniversityhospital.nhs.uk/main.cfm

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)
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
Other non-profit organizations

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

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	01/11/2014		Yes	No
Results article	results	01/06/2016		Yes	No