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The impact of n-3 fatty acids supplementation on the content of lipids in the pregnant women and the fetus

Submission date
25/10/2016

Recruitment status
No longer recruiting

Registration date
09/11/2016

Overall study status
Completed

Last Edited
27/11/2020

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
For women who plan to become pregnant, it is important that they eat a healthy diet and are well nourished before they conceive. This is beneficial both for the mother and also the developing fetus. A healthy diet is important. This includes omega-3 fatty acids such as eicosapentaenoic acid (EPA) and docosahexenoic acid (DHA); these are thought to be critical for the baby's brain and eye development. The aim of this research is to investigate whether taking omega-3 dietary supplements during pregnancy increases the amount found in the women's blood and also the blood supplying the fetus.

Who can participate?
Women pregnant with one baby who are a healthy weight.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 take capsules containing 360 mg EPA (eicosapentanoic) and 240 mg DHA (docosahexanoic acid) every day during their pregnancy starting from the 14th week of gestation until delivery. Participants in group 2 do not take the supplements during pregnancy. At the time the baby is born, blood samples are taken from the mot er and also the umbilical cord to measure total fat (lipid) levels in the blood and also separated fat components, such as fatty acids, triacylglycerols and cholesterol.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Department of Obstetrics and Gynecology School of Medicine Mostar (Bosnia and Herzegovina)

When is the study starting and how long is it expected to run for?
May 2013 to November 2017

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Soldo Dragan
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
-

Study information

Scientific Title
The impact of EPA and DHA supplementation on the content of lipids in the pregnant women and the fetus

Study objectives
The aim of this research was to present the contents and the concentration of free fatty acids in the group of pregnant women which used the supplementation of n-3 fatty acids and the control group of pregnant women which did not use such supplementation of n-3 fatty acids.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee School of Medicine University of Mostar, 29/13/2013, ref. 2944/13

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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

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

Interventions
Participants are randomly allocated to one of two groups:
1. Intervention group: Participants take capsules containing 360 mg EPA (eicosapentanoic) and 240 mg DHA (docosahexanoic acid) per day during pregnancy, from baseline (14th week of gestation) until delivery.
2. Control group: Participants did not used the supplementation of n-3 fatty acids during pregnancy.

Throughout the study, participants attend standard visits at Clinics. At delivery samples of blood from mother and umbilical cord are taken in order to measure levels of total lipids and separated lipid fractions: phospholipids, triacylglycerols, free fatty acids and cholesterol esters.

Intervention Type
Supplement

Primary outcome measure
1. Concentration of n-3 fatty acids in total serum lipids, measured using gas chromatography at the end of pregnancy/delivery
2. Concentration of n-3 fatty acids in umbilical vein serum, measured using gas chromatography at time of birth
3. Concentration of monounsaturated fatty acids in serum total lipids of umbilical vein serum, measured by gas chromatography at time of birth
4. Concentration of monounsaturated fatty acids in serum total lipids of the mother's serum, measured by gas chromatography at the end of pregnancy

Secondary outcome measures
Weight of mother, measured by weighing scale at recruitment, 20th week of gestation, 30th week of gestation and before delivery

Overall study start date
24/05/2013

Completion date
30/11/2017

Eligibility

Key inclusion criteria
1. Healthy pregnant women
2. Single pregnancy
2. BMI (< 25kg/m2)
3. Provision of informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
87 individual participants

Total final enrolment
87

Key exclusion criteria
1. Pregnancy terminated as preterm delivery
2. Pregnant women with chronic illness
3. Pregnant women with gestational diabetes mellitus or preeclampsia

Date of first enrolment
13/06/2013

Date of final enrolment
30/11/2017

Locations

Countries of recruitment
Bosnia and Herzegovina

Study participating centre
Department of Obstetrics and Gynecology School of Medicine Mostar
Kralja Tvrtka, b.b.
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Sponsor information

Organisation
University of Mostar, School of Medicine

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Sponsor type
University/education

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http://mef.sve-mo.ba/

ROR
https://ror.org/00v89p354

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication of results data in a peer-reviewed journal.

Intention to publish date
01/11/2018

Individual participant data (IPD) sharing plan
Please contact dragan.soldo3@tel.net.ba or josip.djelmis@zg.t-com.hr for access.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	25/02/2019	27/11/2020	Yes	No