

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	<input type="checkbox"/> Prospectively registered
Registration date 09/11/2016	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 27/11/2020	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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 mother 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

Protocol serial number
-

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

Study type(s)

Prevention

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 use 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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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.

Mostar

Bosnia and Herzegovina

88000

Sponsor information**Organisation**

University of Mostar, School of Medicine

ROR

<https://ror.org/00v89p354>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

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