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Preservation of insulin C-peptide in pregnant women with type 1 diabetes mellitus

Submission date
08/09/2016

Recruitment status
No longer recruiting

Registration date
15/09/2016

Overall study status
Completed

Last Edited
10/10/2023

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
Diabetes mellitus is a life-long condition where a person is unable to control their blood sugar levels. There are two main types of diabetes, type 1 (around 10% of cases) and type 2. In type 1 diabetes (T1DM) the immune system attacks specialised cells in the pancreas called beta cells (which are responsible for producing the hormone insulin). This means that the sufferer is unable to produce enough insulin to effectively control their blood sugar levels and so regularly inject insulin in order to keep their blood sugar levels in a healthy range. When insulin is made in the pancreas, another molecule called C-peptide is also produced. C-peptide does not affect blood sugar, but as it is found in equal amounts to insulin, testing C-peptide levels is a good way of finding out how much insulin there is in the body. Some studies have shown that fatty acids may be able to protect the pancreas, as well as helping promote normal growth of a baby during pregnancy. The aim of this study is to find out what the effects are when pregnant women with type 1 diabetes take fatty acid supplements on C-peptide and blood sugar control.

Who can participate?
Pregnant women aged between 18 and 40 with type 1 diabetes.

What does the study involve?
Women are randomly allocated to one of two groups. Those in the first group take supplements containing fatty acids (eicosapentanoic acid (EPA) and docosahexanoic acid (DHA)) at meal times from the start of the study (when they are 9 weeks pregnant) until they have their baby. Those in the second group take supplements containing a placebo (dummy pill) at meal times from the start of the study until delivery. At the start of the study and then when the women are 20 and 30 weeks pregnant, and at the time of delivery, blood samples are taken to assess how well they are managing their blood sugar levels.

What are the possible benefits and risks of participating?
Women who take the fatty acid supplements may benefit from lower levels of C-peptide, which could mean that they need to take less insulin. There is also evidence that taking fatty acids during pregnancy could aid the development of their baby's brain. There are no notable risks involved with participating.

Where is the study run from?
Department of Obstetrics and Gynecology School of Medicine Zagreb (Croatia)

When is the study starting and how long is it expected to run for?
December 2013 to September 2019

Who is funding the study?
Ministry of Science, Education and Technology of the Republic of Croatia (Croatia)

Who is the main contact?
Prof. Josip Djelmis
josip.djelmis@zg.t-com.hr

Contact information

Type(s)
Scientific

Contact name
Prof Josip Djelmis

ORCID ID
https://orcid.org/0000-0002-7332-5936

Contact details
Deparment of Obstetrics and Gynecology
School of Medicine
University of Zagreb
Petrova 13
Zagreb
Croatia
1000
+385 (0)1 4578330
josip.djelmis@zg.t-com.hr

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title

The impact of EPA and DHA supplementation on C-peptide preservation in type 1 diabetic pregnant women

Study objectives
The aim of this study is to find the impact of eicosapentanoic acid (EPA) and docosahexanoic acid (DHA) supplementation on secretion of fasting C-peptide in pregnant women with type 1 diabetes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee School of Medicine University of Zagreb, 12/12/2013, ref: 021-1/206 A-13

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Type 1 diabetes mellitus in pregnant women

Interventions
Participants are randomly allocated to one of two groups:
Intervention group: Participants take capsules containing 60mg EPA (eicosapentanoic) and 308 mg DHA (docosahexanoic acid) twice a day at mealtimes during pregnancy, from baseline (9th week of gestation) until delivery.
Control group: Participants take capsules containing a placebo twice a day at mealtimes during pregnancy, from baseline (9th week of gestation) until delivery.

Throughout the study, participants attend standard visits at Clinics at 20th week of gestation, 30th week of gestation and at delivery. At these visits, samples of blood are taken in order to measure levels of fasting C-peptide concentration, level of FPG and HbA1c.

Intervention Type
Supplement

Primary outcome(s)
FC-peptide concentration is measured by the electrochemiluminescence immunoassay “ECLIA” at baseline, 20 weeks gestation, 30 weeks gestation and at delivery.

Key secondary outcome(s))
Current secondary outcome measures as of 10/09/2020:
1. Glycated hemoglobin (HbA1c) is measured from blood samples taken at baseline, 20 weeks gestation, 30 weeks gestation and at delivery
2. Fasting plasma glucose (FPG) is measured using the fasting plasma glucose test using blood

samples taken at baseline, 20 weeks gestation, 30 weeks gestation and at delivery
3. Birth weight of infants is measured by pediatrics after delivery
4. Total lipid profile measured from blood samples (serum) taken at baseline, 2nd and 3rd trimester and at delivery (from mothers and from umbilical cord)

Previous secondary outcome measures:
1. Glycated hemoglobin (HbA1c) is measured from blood samples taken at baseline, 20 weeks gestation, 30 weeks gestation and at delivery
2. Fasting plasma glucose (FPG) is measured using the fasting plasma glucose test using blood samples taken at baseline, 20 weeks gestation, 30 weeks gestation and at delivery
3. Birth weight of infants is measured by pediatrics after delivery

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. Pregnant women
2. Diagnosis of type 1 diabetes
3. Provision of informed consent
4. Aged between 18-40 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
40 years

Sex
Female

Total final enrolment
111

Key exclusion criteria
Type 1 diabetic patients whose pregnancy terminated as preterm delivery

Date of first enrolment

19/12/2013

Date of final enrolment
30/05/2021

Locations

Countries of recruitment
Croatia

Study participating centre
Department of Obstetrics and Gynecology School of Medicine Zagreb
Petrova 13
Zagreb
Croatia
10000

Sponsor information

Organisation
University of Zagreb, School of Medicine

ROR
https://ror.org/00mv6sv71

Funder(s)

Funder type
Government

Funder Name
Ministry of Science, Education and Technology of the Republic of Croatia

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Josip Djelmis (josip.djelmis@zg.t-com.hr) and Marina Horvaticek (marina.horvaticek@gmail.com). Data will be shared in agreement with another parties.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2017		Yes	No
Results article		01/12/2021	10/10/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes