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

Submission date	<b>Recruitment status</b> No longer recruiting	Prospectively registered		
08/09/2016		[] Protocol		
Registration date	Overall study status	[] Statistical analysis plan		
15/09/2016	Completed	[X] Results		
Last Edited 10/10/2023	<b>Condition category</b> Nutritional, Metabolic, Endocrine	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

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### Contact details

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## Additional identifiers

EudraCT/CTIS number Nil known

**IRAS number** 

**ClinicalTrials.gov number** Nil known

**Secondary identifying numbers** 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

**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

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 measure

FC-peptide concentration is measured by the electrochemiluminescence immunoassay "ECLIA" at baseline, 20 weeks gestation, 30 weeks gestation and at delivery.

### Secondary outcome measures

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

Pasting 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
Birth weight of infants is measured by pediatrics after delivery

### Overall study start date

01/12/2013

### **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

**Age group** Adult

**Lower age limit** 18 Years

**Upper age limit** 40 Years **Sex** Female

**Target number of participants** 150 individual participants

**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

### Sponsor details

Salata 3 Zagreb Croatia 1000

**Sponsor type** University/education

### ROR

# Funder(s)

**Funder type** Government

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

## **Results and Publications**

### Publication and dissemination plan

Planned publication of results data in a peer reviewed journal.

### Intention to publish date

30/06/2022

### 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?
<u>Results article</u>	results	01/08/2017		Yes	No
Results article		01/12/2021	10/10/2023	Yes	No