

In vivo materno-fetal fatty acid transfer in normal and obese pregnancy

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Registration date 12/12/2017	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 23/11/2020	Condition category Nutritional, Metabolic, Endocrine	<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

Maternal obesity during pregnancy has been linked with higher fetal fat mass, which could be related to higher incorporation of circulating fatty acids into fetal adipose (fat) tissue, promoting fetal programming of obesity. However, the role of the placenta in the selective transfer of specific fatty acids is unknown. Previous studies on women with gestational diabetes have found disturbed fatty acid transfer to the fetus which might also affect the neurodevelopment of the newborn. Similar results could also occur in maternal obesity but it is unknown. The aim of this study is to assess the transfer of the different fatty acids in obese mothers compared to healthy pregnant women.

Who can participate?

Pregnant women aged 18-40 who are planning to undergo an elective caesarean section at term

What does the study involve?

Ten obese and ten normal weight pregnant women take labelled fatty acids orally 12 hours before they undergo a caesarean section. Maternal plasma (blood) samples are taken at different timepoints until delivery, when cord blood and placenta samples are collected. Fatty acid levels are then measured.

What are the possible benefits and risks of participating?

This study attempts to provide better knowledge on the transfer of fatty acids with the aim of improving dietary recommendations for obese pregnant women. Participants might benefit from the results of this study in future pregnancies, as well as the whole population of women of reproductive age. There are no risks for the participating pregnant women or their babies. Labelled fatty acids have been used in previous studies without any side effects. Nevertheless, a medical insurance is signed in order to cover any unlikely negative event.

Where is the study run from?

1. "Virgen de la Arrixaca" Clinical Hospital (Spain)
2. University of Murcia (Spain)
3. Dr. von Hauner Children's Hospital, Ludwig-Maximilians-University Munich (Germany)

When is the study starting and how long is it expected to run for?
February 2012 to October 2017

Who is funding the study?

This work is financially supported in part by the Commission of the European Communities, Projects Early Nutrition, DYNAHEALTH and LIFECYCLE, the European Research Council Advanced Grant META-GROWTH, and the Excellence Network for Maternal and Child Health and Development

Who is the main contact?

Prof. Elvira Larqué

Contact information

Type(s)

Scientific

Contact name

Prof Elvira Larqué

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Additional identifiers

Protocol serial number

KBBE.2011.2.2-03

Study information

Scientific Title

In vivo materno-fetal fatty acid transfer in normal and obese pregnancy

Study objectives

Maternal obesity at conception is considered a major predictor of offspring obesity. The pathophysiological mechanisms involved in the early programming of obesity are not fully understood. This study aimed to investigate the role of materno-fetal transfer of fatty acids in obese pregnant women using stable isotopes.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the Virgen de la Arrixaca Clinical Hospital, 29/04/2013, ref: 04/13

Primary study design

Observational

Study design

Observational case-control study

Study type(s)

Other

Health condition(s) or problem(s) studied

Obesity

Interventions

Ten obese and ten normal weight pregnant women (control) received orally ¹³C-labelled fatty acids 12h before elective caesarean section: oleic acid, linoleic acid and docosahexaenoic acid. Maternal plasma samples were taken before tracer administration and at different timepoints until delivery, when cord blood and placenta samples were collected. ¹³C-enrichment and ¹³C-fatty acid concentrations were determined by gas chromatography combustion isotope ratio mass spectrometry.

Intervention Type

Other

Primary outcome(s)

¹³C-enrichment and ¹³C-fatty acid concentrations in samples of plasma, placenta and cord blood, measured by gas chromatography combustion isotope ratio mass spectrometry at baseline and during the 12h before the cesarean section

Key secondary outcome(s)

¹³C-enrichment and ¹³C-fatty acid concentrations in maternal plasma lipoproteins, measured by gas chromatography combustion isotope ratio mass spectrometry at baseline and during the 12h before the cesarean section

Completion date

30/10/2017

Eligibility**Key inclusion criteria**

1. Singleton pregnancy
2. Age 18-40 years
3. Plan to undergo elective caesarean section at term
4. Omnivorous diet
5. No DHA supplements (last trimester)
6. Non-smoking
7. Normal fetal Doppler scan within the normal reference range (24) on the day before caesarean section

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

20

Key exclusion criteria

Any health problem of the mother or fetus, diabetes, gestational diabetes, preeclampsia

Date of first enrolment

13/05/2013

Date of final enrolment

15/04/2015

Locations**Countries of recruitment**

Germany

Spain

Study participating centre

"Virgen de la Arrixaca" Clinical Hospital

Murcia

Spain

30120

Study participating centre

Department of Physiology, University of Murcia

Murcia

Spain

30100

Study participating centre

Division of Metabolic and Nutritional Medicine, Dr. von Hauner Children's Hospital, Ludwig-Maximilians-University Munich
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Sponsor information

Organisation

Commission of the European Communities

ROR

<https://ror.org/00k4n6c32>

Funder(s)

Funder type

Government

Funder Name

This work is financially supported in part by the Commission of the European Communities, Projects Early Nutrition (FP7-289346), DYNAHEALTH (H2020-633595) and LIFECYCLE (H2020-SC1-2016-RTD), the European Research Council Advanced Grant META-GROWTH (ERC-2012-AdG 322605), and the Excellence Network for Maternal and Child Health and Development (RED SAMID III, RD 16/0022/0009)

Results and Publications

Individual participant data (IPD) sharing plan

According to the Spanish law of Personal Data Protection, the individual data collected are only available for partners on the repository intranet from the European project Early Nutrition (FP7-289346).

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2020	23/11/2020	Yes	No

