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

Submission date	Recruitment status	[_] Prospectively registered
28/11/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/12/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
23/11/2020	Nutritional, Metabolic, Endocrine	

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 Larque

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Observational case-control study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Other

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
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 measure
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

Secondary outcome measures
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

Overall study start date

01/02/2012

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
40 Years

Sex
Female

Target number of participants
20

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
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Spain
30100

Study participating centre
Division of Metabolic and Nutritional Medicine, Dr. von Hauner Children's Hospital, Ludwig-Maximilians-University Munich
Munich
Germany
80337

Sponsor information

Organisation
Commission of the European Communities

Sponsor details
EU
Murcia
Spain
30100

Sponsor type
Government

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

Publication and dissemination plan
Planned publication of the results in peer-reviewed journals in 2018-2019. The protocol and statistical analyses will be published together with the results of the project.

Intention to publish date
30/10/2018

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