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Changes in fetal DNA modification associated with maternal blood sugar during pregnancy

Submission date
06/09/2017

Recruitment status
No longer recruiting

Registration date
13/09/2017

Overall study status
Completed

Last Edited
13/09/2017

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims:
Infants born to mothers with pregnancy diabetes have increased risk of type 2 diabetes later in life. The aim of this study is to examine the extent to which maternal metabolism and habits during pregnancy are related to modifications of genetic material from the fetus during pregnancy. Fetal gene information is collected from the woman's blood during pregnancy using standard blood collection.

Who can participate?:
Scandinavian women aged 25-35 years in early pregnancy. In total, 30 women will be recruited before pregnancy week 12+6. Of these participants, 50% will have a high risk of pregnancy-diabetes while 50% are expected to have a normal pregnancy.

What does the study involve?
This study involves three study visits during pregnancy (all including blood collection from the woman), passive bio-sample collection at delivery (e.g. from the placenta), and one study visit two months after delivery (blood collection from mother and infant). In addition to clinical visits, participating women are followed with continuous monitoring of blood-sugar and physical activity, and report their own weight.

What are the possible benefits and risks of participating?:
There are no direct medical benefits of participating in the study. However, the closer monitoring of blood-sugar in pregnancy could potentially lead to earlier detection of pregnancy-diabetes. The main risk of participating should be potential skin-reactions from devices monitoring blood-sugar and physical activity. Standard blood collection through venipuncture is also associated with a small risk of infection.

Where is the study run from?:
Skåne University Hospital in Lund/Malmö (Sweden)

When is study starting and how long is it expected to run for?:
September 2017 to 2019

Who is the main contact?:
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.0

Study information

Scientific Title

The Diabetogenic Perturbations of the Fetal Methylome Project

Acronym
DIAPRIME

Study objectives
We hypothesize that intrauterine exposure to maternal blood glucose during gestation will correlate with differences in patterns of fetal methylation; fetal methylation patterns will vary by timing and degree of intrauterine exposure to maternal glucose.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethical Review Board in Lund, Sweden, 01/09/2016, ref: 2016/489 with amendment 2016/1098

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Maternal-fetal effects of metabolism in pregnancy

Interventions
Participants attend study visits at three time points in pregnancy (approximately at 12, 26, and 34 gestational weeks) during which maternal blood, questionnaire data on lifestyle, and anthropometry are collected.

Participants are also monitored between study visits with self-reported weight, continuous glucose monitoring and physical activity (wrist accelerometry) from recruitment in early pregnancy to delivery. At delivery, bio-sampling is performed (e.g. placental material and cord blood) and at approximately two months postpartum, additional maternal and infant data is collected, including blood sampling.

Intervention Type
Other

Primary outcome measure
Changes in fetal/placental DNA methylation at three time points in pregnancy are measured using cell-free fetal DNA isolated from maternal blood and next generation sequencing at approximately 12, 26, and 34 gestational weeks.

Secondary outcome measures
1. Maternal physical activity as measured by wrist accelerometer from early pregnancy to delivery
2. Maternal blood-glucose as measured by a continuous glucose monitor and OGTT from early pregnancy to delivery
3. Maternal weight gain and body composition (daily weighing using a medical scale and/or clinically measured using the Styku 3D body scanning system) throughout pregnancy and postpartum

Overall study start date
01/01/2016

Completion date
15/09/2019

Eligibility

Key inclusion criteria
In total, we will recruit around 30 pregnant women:
1. Aged 25-35 before gestational week 12+6

Half of the recruited women (50%) will have a high risk of gestational diabetes mellitus:
1. Family history of diabetes
2. Prior pregnancy affected by diabetes
3. Current obesity

Half of the recruited women (50%) are expected to have a normal pregnancy not complicated by gestational diabetes mellitus (controls).

If a control woman develops gestational diabetes, she will be invited to continue to take part in the study and be monitored as per standard of care; we will then seek to recruit an additional woman to the control arm to ensure an adequate number of participants in the study.

Participant type(s)
Mixed

Age group
Adult

Sex
Female

Target number of participants
30

Key exclusion criteria
1. Not of Scandinavian origin
2. Use of assisted reproductive technology
3. History of three or more first trimester miscarriages
4. Tobacco use (smoking/snus) in the previous three months
5. Diagnosed PCOS
6. History of gastric bypass surgery
7. Type 1 diabetes
8. Non-Swedish speaker
9. Planned termination of pregnancy or planning to give up infant for adoption

Date of first enrolment
20/09/2017

Date of final enrolment
15/09/2018

Locations

Countries of recruitment
Sweden

Study participating centre
Skåne University Hospital
Lund/Malmö
Sweden
222 41

Sponsor information

Organisation
Lund University

Sponsor details
Box 117
Lund
Sweden
221 00

Sponsor type
University/education

Website
www.lu.se

Organisation
Skåne University Hospital

Sponsor details
Getingevägen 4
Lund
Sweden
222 41

Sponsor type
Hospital/treatment centre

Organisation
Lund University

Sponsor details

Sponsor type
Not defined

Website
http://www.lunduniversity.lu.se/

ROR
https://ror.org/012a77v79

Funder(s)

Funder type
Charity

Funder Name
The European Foundation for the Study of Diabetes

Funder Name
The Swedish Heart-Lung Foundation

Funder Name
Novo Nordisk Foundation

Results and Publications

Publication and dissemination plan
Planned publication in relevant peer-reviewed scientific journal.

Intention to publish date
01/09/2020

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date