

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

Submission date 06/09/2017	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 13/09/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 13/09/2017	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Protocol serial number

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

Primary study design

Observational

Study design

Observational cohort study

Study type(s)

Other

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

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Sponsor information

Organisation

Lund University

Organisation

Skåne University Hospital

Organisation

Lund University

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**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