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Predictive markers of gestational diabetes mellitus in first and early second trimester of pregnancy

Submission date
09/03/2017

Recruitment status
No longer recruiting

Registration date
20/03/2017

Overall study status
Completed

Last Edited
18/10/2018

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
Gestational diabetes (GD) occurs when pregnant women cannot produce enough insulin (a type of hormone) to control their blood sugar levels. GD can cause severe pregnancy complications both during birth and after birth. GD can happen to any pregnant women but those who have higher body mass index (measure of weight versus height), have had large babies before or have family with diabetes are at a higher risk. GD can cause premature births (earlier than the 37th week of pregnancy), high blood pressure, babies born with jaundice (yellowing of the skin due to low blood sugar), too much amniotic fluid in the womb and can even result in a stillbirth. GD does not usually have any symptoms therefore women must be screened for GD during pregnancy. Women are usually screened, especially if they have any of the risk factors, using the oral glucose tolerance test (OCTT) around their 24th to 28th weeks of pregnancy. This involves a blood test prior to eating or drinking, drinking a sugary drink and then giving another blood sample to see how the body can handle to sugar. However, it could be possible to detect GD earlier in pregnancy using blood tests. There are certain blood markers (adiponectin, leptin, SHBG and lipid profile) that can be used as early indicators for developing gestational diabetes later in pregnancy. Therefore the aim of this study is to see if these markers are accurate at determining if women will form gestational diabetes later in pregnancy.

Who can participate?
Women over the age of 18 who are pregnant with one baby.

What does the study involve?
Participants who are 11-13 (plus six days) weeks pregnant have a blood sample taken from them which is then frozen and stored. At 24 to 28 weeks of gestation, participants undergo the oral glucose tolerance test to diagnose for gestational diabetes. Participants are then allocated to one of two groups. Those in the first group all have pregnancies complicated by diabetes. Those in the second group all have normal pregnancies. The stored blood samples are then analysed for levels of lipids (fats), cholesterol, and other markers to see if there are any indications of gestational diabetes in blood prior to being diagnosed by comparing the two groups.

What are the possible benefits and risks of participating?
There are no notable benefits or risks with participating. Participants may feel some discomfort when giving blood samples.

Where is the study run from?
First Department of Obstetrics and Gynecology, University of Athens, Alexandra Hospital (Greece)

When is the study starting and how long is it expected to run for?
April 2017 to December 2018

Who is funding the study?
University of Athens Alexandra Hospital (Greece)

Who is the main contact?
Professor George Daskalakis

Contact information

Type(s)
Public

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Adiponectin, leptin, sex hormone-binding globulin (SHBG) and lipid profile values during the first or early second trimester of pregnancy and the subsequent risk of gestational diabetes mellitus later in pregnancy

Study objectives
Adiponectin, leptin, sex hormone-binding globulin (SHBG) and lipid profile values during the first or early second trimester of pregnancy may be used as early markers to target women at increased risk for developing gestational diabetes later in pregnancy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Scientific Board of Alexandra Hospital, 23/11/2016, ref: 717/09-11-2016

Study design
Single-centre case-control study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Gestational diabetes mellitus

Interventions
At 11 - 13 (plus six days) weeks of pregnancy, blood samples from pregnant participants are collected and stored at -80 C.

At 24 to 28 weeks of gestation, according to the results of the 2 hour 75 gr Oral Glucose Tolerance Test (OGTT), two groups of 75 participants per group are formed. The glucose test is done to diagnose gestational diabetes and determine who is in the case or the control groups. The test involves participants giving a blood sample prior to eating or drinking, drinking a sugary drink and then giving another blood sample to see how the body can handle to sugar. Participants whose pregnancies are complicated with gestational diabetes are allocated to group one (the case group). Participants with normal pregnancies are allocated to group two (the control group). The target number of participants for each group is obtained using statistical analysis.

The stored blood samples of those two groups are analysed for the quantitative determination of serum adiponectin, leptin, SHBG and lipid profile (total cholesterol, triglycerides, HDL cholesterol, LDL cholesterol). The measurements of lipid profile are also be used for the determination of the atherogenic markers LDL cholesterol, HDL cholesterol, triglycerides, HDL cholesterol and total cholesterol, HDL cholesterol.

The serum measurements of the above first trimester markers of the two groups (case vs control) are recorded in a database and analyzed with the appropriate statistical method.

Intervention Type
Biological/Vaccine

Primary outcome measure
1. Serum adiponectin is measured using blood samples at 11-13 (plus six days) weeks of pregnancy
2. Serum leptin measured using blood samples at 11-13 (plus six days) weeks of pregnancy

Secondary outcome measures
1. Serum sex hormone-binding globulin (SHBG) are measured using blood samples at 11-13 (plus six days) weeks of pregnancy
2. Lipid profile (total cholesterol, triglycerides, HDL cholesterol, LDL cholesterol) are measured usng blood samples at 11-13 (plus six days) weeks of pregnancy
3. Atherogenic markers (LDL cholesterol, HDL cholesterol, triglycerides, HDL cholesterol and total cholesterol, HDL cholesterol) are measured using blood samples at 11-13 (plus six days) weeks of pregnancy

Overall study start date
01/10/2016

Completion date
31/05/2019

Eligibility

Key inclusion criteria

1. Female
2. Age over 18 years
3. Singleton pregnancies

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Target total recruitment of participants: 150 participants (75 participants per group)

Key exclusion criteria
1. Age under 18 years
2. Multiple pregnancy
3. Pre-existing type 1 or type 2 diabetes mellitus
4. Chronic hypertension
5. Preeclampsia, eclampsia
6. Hypothyroidism
7. Pre-existing renal or hepatic impairment
8. Other chronic diseases (e.g. valvular heart disease)
9. Vaginal bleeding (e.g. placental abruption)
10. Special diets (e.g. lactose intolerance)
11. Inadequate monitoring during pregnancy

Date of first enrolment
01/04/2017

Date of final enrolment
31/01/2019

Locations

Countries of recruitment
Greece

Study participating centre
Alexandra Hospital
First Department of Obstetrics and Gynecology
80 Vasilissis Sofias Avenue
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Sponsor information

Organisation
University of Athens

Sponsor details
First Department of Obstetrics and Gynecology
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03xawq568

Funder(s)

Funder type
University/education

Funder Name
National and Kapodistrian University of Athens

Alternative Name(s)
University of Athens

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Greece

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal. Study results will also be used within a PhD study.

Intention to publish date
31/05/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study is not expected to be made available due to confidentiality reasons. The data will be held at the First Department of Obstetrics and Gynecology, Alexandra Hospital.

IPD sharing plan summary
Not expected to be made available