PRegnancy Outcomes and Maternal Insulin Sensitivity

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1. To investigate the glucose and insulin responses after the MTT enriched with labelled glucose early (12-16 weeks), mid pregnancy (24-28 weeks) and postpartum (3 months) 2. Compare the MTT results with the standard OGTT testing at 24-28 weeks (in...

Ethical review	Approved WMO
Status	Completed
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational invasive

Summary

ID

NL-OMON48381

Source
ToetsingOnline

Brief title
PROMIS

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Pregnancy, labour, delivery and postpartum conditions
- Lifestyle issues

Synonym
Gestational diabetes mellitus, pregnancy diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,Danone Nutricia Research;TKI

Intervention

Keyword: glucose metabolism, growth, Overweight, Pregnancy

Outcome measures

Primary outcome

-Fasting levels of: glucose and insulin

-PP responses of: glucose and insulin collected at t=0,10, 20,30,45,60,90 and 120 min after the MTT or OGTT.

Secondary outcome

Secondary study parameters:

- fasting levels of total cholesterol, high density lipoprotein (HDL), triglycerides, free fatty acids, HbA1c, human placental lactogen, leptin, and cortisol.

- Maternal anthropometrics and adiposity measures

- Fetal growth and adiposity sonography measures

- Neonatal growth and adiposity measures

- Maternal, fetal and neonatal complications

Exploratory sudy parameters:

- fasting and postprandial levels of stable glucose isotopes

- neonatal eating behaviour

- Lifestyle questionnaires

Study description

Background summary

Today, gestational diabetes mellitus (GDM) is affecting 1 out of 7 pregnancies worldwide, but actual rates between regions and countries show considerable variation. The world health organization (WHO) accounts a body mass index (BMI) >=25 kg/m2 as a risk factor for screening GDM. However most countries, including the Netherlands, use a BMI cut off of >=30 kg/m2. GDM is standardly diagnosed with a 75 g carbohydrate oral glucose tolerance test (OGTT) between week 24-28 of gestation. The exact prevalence of GDM in the Netherlands is unknown but is estimated to be between 3 to 5% using the Dutch Gynecology and Obstetrics risk factors (NVOG)5. It is known that the OGTT is not well reproducible. In contrast, the meal tolerance test (MTT), which contains only 50 grams of carbohydrates, is more efficient to detect more subtle changes in postprandial (PP) glucose more efficiently. Research has shown that about 60% of GDM patients already have deviations in metabolic markers other than glucose in the first or second trimester. In addition, the *hyperglycemia and adverse pregnancy outcome* (HAPO) study demonstrated a linear relationship between the level of hyperglycemia and adverse pregnancy outcomes, suggesting that the current diagnostic approach may miss a part of the problems associated with maternal GDM. The present study will focus on the associations between insulin sensitivity in the mother in early pregnancy and fetal and neonatal outcomes with emphasis on growth and body composition.

Study objective

1. To investigate the glucose and insulin responses after the MTT enriched with labelled glucose early (12-16 weeks), mid pregnancy (24-28 weeks) and postpartum (3 months)

2. Compare the MTT results with the standard OGTT testing at 24-28 weeks (in this study in week 28) in pregnancy

3. To study possible associations of insulin sensitivity and plasma glucose and lipid measures with defined pregnancy outcomes for both mother and child:
- Pregnancy complications,
- Postnatal insulin sensitivity recovery,
- Weight retention,
- Fetal growth,
- Birth outcomes (e.g. body weight infant),
- Infant growth
- Growth and body composition development up to 6 months of age.

4. The exploratory outcomes of the PROMIS study will inform the development of strategies to improve outcomes via targeted nutritional, lifestyle and/or pharmaceutical intervention during pregnancy and lactation in subsequent

studies

Study design

The PROMIS study is a prospective exploratory cohort study where maternal insulin sensitivity during pregnancy will be monitored in association to (adverse) offspring outcomes. In the beginning of the second trimester (week 12-16) a MTT enriched with labeled glucose will be given to the study participants as will be done mid pregnancy (week 24-28) to compare to the standard OGTT (week 24-28). In addition, the MTT will be given to the study participants 3 months postpartum to study insulin sensitivity, remission of GDM or progression from GDM to diabetes mellitus type 2 (DM2). Maternal anthropometrics during pregnancy as well as fetal sonography and neonatal adiposity and anthropometrics will be monitored throughout the study period.

Study burden and risks

Our study aims to monitor metabolic responses in more detail by using an MTT and comparing the results to later (standard) assessment during pregnancy. The addition of stable labelled glucose isotopes to the MTT will provide us more detailed information on glucose appearance versus clearance and possible underlying alterations in insulin responses and sensitivity prior to GDM development. There will be a total of 8 visit moments. Participants will undergo a 2 hour PP test 3 times during pregnancy (MTT 2x, OGTT 1x). This requires a substantial time investment and commitment for which the participant should be rested with an intravenous catheter from which regular blood drawings are taken. There is a modest risk for phlebitis, an hematoma on the arm. The stable labelled glucose isotopes do not pose any health risk for mother and child. The child will undergo several detailed anthropometric measurements until 6 months of age.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Healthy singleton pregnant women (10-12 weeks of gestation)
- BMI >=25 kg/m2
- Fasting Blood Glucose (FBG <=7.0 mmol/l)
- Dutch or English speaking
- Written informed consent

Exclusion criteria

- Serious health complications (Hypertension, Hyperlipidemia, Asthma, Haemochromatosis) or medication use that influence the glucose metabolism or fetal growth (e.g. corticosteroids).
- Multiple pregnancy
- pre-existing Diabetes type 1 and 2 defined as FBG >=7.0 mmol/l or use of diabetes medication
- Participation in any other studies involving the investigation of medication or nutritional products or antibiotic use in the two weeks prior to entry into the study
- HIV/Hepatitis
- Expectation of non-compliance to the study protocol, among others, a fear of needles
- Known allergies or intolerances for nutritional ingredients in the MTT
- Psychological dysfunctions

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	06-02-2020
Enrollment:	130
Type:	Actual

Ethics review

Approved WMO Date:	18-07-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	17-12-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL68845.042.19