GLIMP II study - An observational study to assess the role of diet and nutrient status and other lifestyle and risk factors in gestational diabetes

Published: 11-03-2015
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Primary :To compare diet quality and nutrient status before and during pregnancy of women who develop GDM with those who have normal blood sugar levelsSecondary:*To compare body composition before (and during) pregnancy of women who develop GDM with...

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

Summary

ID

NL-OMON44490

Source
ToetsingOnline

Brief title
GLIMP II

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
gestational diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Diet, Epidemiology, Gestational diabetes, Lifestyle

Outcome measures

Primary outcome

Dutch Healthy Diet index score which is a measure of overall diet quality

Secondary outcome

Nutrient status for vitamin D, folic acid, vitamin B12, vitamin B6 and iron

Dietary intake of food groups, individual foods, macronutrients and

micronutrients

BMI (weight and height)

Body fat percentage

Physical activity level

Cardiometabolic risk factors (blood pressure, serum total and HDL cholesterol,

triglycerides, liver enzymes [CRP, ALAT, ASAT, AF and GTT])

Adiponectin and other adipokines (e.g. leptin)

Study description

Background summary

Gestational diabetes mellitus (GDM) is one of the most common metabolic complication during pregnancy, affecting 1-18% of all pregnancies. GDM increases risk of adverse pregnancy outcomes and has been related to significant short-term and long-term adverse health outcomes for both mothers and offspring, including increased risk of adverse pregnancy outcomes, type 2 diabetes and obesity. Although treatment is effective in reducing adverse pregnancy outcomes, prevention might be more desirable as this might be more effective in reducing long term adverse health outcomes. Diet is often linked

as modifiable risk factor to GDM, however there is still a knowledge gap regarding the association between diet and GDM. This needs to be addressed before designing prevention intervention studies.

Study objective

Primary :
To compare diet quality and nutrient status before and during pregnancy of women who develop GDM with those who have normal blood sugar levels

Secondary:
*To compare body composition before (and during) pregnancy of women who develop GDM with those who have normal blood sugar levels
*To compare physical activity level before and during pregnancy of women who develop GDM with those who have normal blood sugar levels
*To compare cardiometabolic risk factors and adipokines before and during pregnancy of women who develop GDM with those who have normal blood sugar levels

Study design

This is an observational study using a whole pregnancy approach to assess the association between diet and GDM. This includes measurements before the pregnancy, measurements during pregnancy (at 12 weeks of gestation and at 24 weeks of gestation) and after pregnancy (6 weeks after delivery). Every measurement moment consists of a physical examination, blood sampling + an oral glucose tolerance, several questionnaires assessing dietary intake, eating behaviour, physical activity, medical history and quality of life , two times filling in a 24-hour recall, collecting 24 hour urine and wearing a accelerometer for 7 consecutive days. Additionally at the first measurement moment a DXA-scan is done to measure body fat percentage.

In a substudy umbilical cord blood, a piece of the umibilcal cord and a buccal swap of the child (at age 6-9 weeks) will be collected These measurements will allow us to investigate the effect of gestational diabetes on the epigenome of the child.

Study burden and risks

Subjects will be asked for 4 visits to the study centre (approximately 30 minutes per examination), 4 visits to one of the involved hospitals (120 minutes per visit), 8 times filling in a 24-hour recall (30 minutes per recall), wearing 4 times a week an accelerometer and collecting 4 times 24 hour urine.

Venapunctures can occasionally cause a local hematoma or bruise and some participants may report pain or discomfort. Measurement of body fat percentage at T0 will be done using DXA. This procedure uses a very low dose of X-ray, comparable to that of skiing or walking half a day in the mountains.

Benefit for the individual participants is that they receive information on their BMI, blood pressure, total and HDL-cholesterol, triglyceride and glucose level, with interpretation based on the guidelines of Dutch general practitioners (NHG-standaard), and the advice to contact their general practitioner when values are to be considered high.

Substudy: collection of umbilical cord blood, a piece of umbilical cord and a buccal swap are considered non-invasive and safe for both mother and child.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Children (2-11 years)

Elderly (65 years and older)

Inclusion criteria

*Female
*Age from 18 -40
*Pregnancy wish (wants to get pregnant within one year at time of recruitment) OR * 24 weeks pregnant at time of recruitment
*Competent to make own decisions
*Written informed consent obtained

Exclusion criteria

*Not able to read and speak Dutch
*>24 weeks pregnant at time of recruitment
*Type 1 diabetes mellitus
*Type 2 diabetes mellitus

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-06-2015
Enrollment:	455
Type:	Actual

Ethics review

Approved WMO

Date:	11-03-2015
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	05-10-2015
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	06-09-2016
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)

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	NL50554.081.14