Optimisation of the (pre)analysis for diabetes gravidarum.

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In this study we will assess the optimal analytical conditions for routine laboratory GDM screening in the Netherlands, possible discrepancies in clinical outcome due to (pre)analytical variation and the applicability of POCT testing in GDM...

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

Summary

ID

NL-OMON40427

Source
ToetsingOnline

Brief title
Optimisation of the (pre)analysis for diabetes gravidarum.

Condition

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

Synonym
Diabetes gravidarum, pregnancy diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Amphia Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Analysis, Diabetes, Laboratory, Pregnancy

Outcome measures

Primary outcome

Part 1) Stability of in vitro glucose levels after phlebotomy under a variety of (pre)analytical variables, such as the choice of the collection tube and the optimal turn-around-time. Part 2) the applicability of POCT testing in the diagnosis of GDM in comparison with phlebotomy and determination of the possible clinical misdiagnosis of GDM if one deviates from the optimal (pre)analytical variables.

Secondary outcome

None

Study description

Background summary

Pregnancy diabetes is associated with an increased risk of maternal, foetal and neonatal mortality and morbidity. In order to prevent this, glucose levels should be regulated as well as possible, both during preconception and pregnancy. In the Netherlands, approximately 400 pregnant, type I diabetic women are treated (frequency 0,2%). Similar numbers are found for type II diabetics. In addition, approximately 3-5% of all pregnant women develop diabetes gravidarum (GDM), described as diabetes diagnosed during pregnancy. Although national guidelines do exist, there is no consensus for the laboratory analysis of glucose as well as for screening and treatment of GDM.

Study objective

In this study we will assess the optimal analytical conditions for routine laboratory GDM screening in the Netherlands, possible discrepancies in clinical outcome due to (pre)analytical variation and the applicability of POCT testing

in GDM screening.

Study design

This study consists of 2 consecutive parts. Part 1) blood will be collected via venapuncture from healthy volunteers to identify the optimal (pre)analytical conditions for glucose analysis. Blood will be collected in a variety of collection tubes (sodium-fluoride(NaF)-EDTA, NaF-oxalate, NaF-EDTA Citrate and lithium-heparin) and compared to recommended procedures. Glucose levels will be determined after set time points to mimic routine daily laboratory practice. Part 2) An oral glucose tolerance test GTT (75g) will be performed in pregnant women. Subjects will be phlebotomized according to the most optimal protocol (determined in part 1) prior to and 120 minutes after the start of the GTT and, simultaneously, glucose levels are determined by point of care testing (POCT). With respect to the current study design; we would like to stress that the study population will consist of patient in whom GTT is already clinically indicated on forehand, and the inclusion is not part of the study design.

Study burden and risks

Part 1) The burden will comprise a single phlebotomy. Part 2) Phlebotomy/POCT during OGTT. Apart from the POCT testing, the GTT does not deviate from the standard operating procedure in pregnant women.

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

Part 1. Healthy volunteers.;Part 2. Pregnant women with an indication (as determined by a gynaecologist) to undergo an oral glucose tolerance test.

Exclusion criteria

In the first part of the experiment, there are no exclusion criteria, as the sampled population should (ideally) represent a random population.;In the second part of the experiment, subjects are excluded from analysis if the OGTT is not completed for any reason. To assess pregnancy diabetes, it is important to discriminate from a prior underlying diabetes; therefore, patients will be excluded when diabetes was already present before pregnancy.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-09-2014
Enrollment:	120

Type:	Actual

Ethics review

Approved WMO Date:	17-06-2014
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	03-11-2014
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	12-06-2015
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL46462.015.13