Comparison of Point-Of-Care testing and venouS blood glucose at the oral Glucose TolerAnce test in pRegnancy

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24013

Source
NTR

Brief title
POCT-SUGAR

Health condition

Gestational Diabetes, Pregnancy

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum
Source(s) of monetary or material Support: Not applicable

Intervention

Outcome measures

Primary outcome

Level of agrement between plasma levels and capillary samples.

Secondary outcome

To determine the number of diagnosed patients with GDM detected by POCT.
To evaluate whether adjusted cut-offs for the POCT can be found to minimize false-positive and false-negative results compared to venous blood sampling.

Study description

Background summary

Pregnancy is accompanied by a physiological insulin resistance, resulting from increased maternal adiposity and the insulin-desensitising effects of hormonal products of the placenta (1). In normal pregnancy, pancreatic β-cells increase their insulin production, to compensate for the insulin resistance, through hyperplasia, hypertrophy and hyper function to compensate for the insulin resistance and to maintain normal blood glucose levels (2-4). When insulin secretion fails to compensate for the increased insulin needs during pregnancy due to β-cell dysfunction pregnant woman are prone to Gestational diabetes mellitus (GDM) (5).

GDM is defined as any degree of glucose intolerance with onset or first recognition during pregnancy (6). Over the past twenty years there is an increase prevalence of GDM, depending on the screening method used and diagnostic criteria. GDM is characterized by increased risk of macrosomia and birth complications and an increased risk of maternal type two diabetes mellitus after pregnancy (Hod et al, 2015). The association of macrosomia and birth complications with oral glucose tolerance test (OGTT) results is continuous, with no clear inflection points (7). In other words, risks increase with progressive hyperglycemia. Treating hyperglycemia in pregnancy decreases the risk of adverse pregnancy outcome (8).

The International Association of the Diabetes and Pregnancy Study Groups (IADPSG) has published guidance recommending the 75 g OGTT with lowered thresholds (compared with WHO 1999 criteria) in the light of HAPO study findings (9). Lowering the diagnostic threshold will increase the incidence of the diagnosis of GDM. Evidence indicates that treatment of women with mild to moderate GDM reduces the risk of adverse perinatal outcomes.

Current recommendations on the criteria for diagnosis are varying across different guidelines (WHO, NICE 2015). It is clear that the choice of test and diagnostic criteria varies within and between countries (10). In the Netherlands screening for GDM is based on the ‘one-step’ strategy. The diagnosis of GDM is made when one of the three plasma glucose levels of the OGTT meet or exceed the criteria proposed by the IADPG.

The use of glucometers for monitoring and managing diabetes mellitus has been extensively studied and is generally accepted as a part of care of diabetic patients. Compared with laboratory glucose testing, POCT is a good alternative at the time of the OGTT to screen for GDM considering reducing laboratory cost, convenience for patients and the immediate availability of results (Claver et al., 2020). When using POCT for glucose analysis in the future POCT could take place at home, because the OGTT is no longer dependent on laboratory analysis. In order to use POCT to diagnose GDM its reliability and validity must match the

gold standard, the laboratory analysis (Hod et al., 2015).

In previous studies there is controversy about the validity of POCT to screen for GDM. There is a large heterogeneity of the studied glucometers, which means that results cannot be directly compared with each other. Previous studies showed variations in the concordance of POCT devices compared to laboratory methods. There are several studies with a low sample size, who report a higher glucose value in capillary samples than in venous samples, applying the same cut-off criteria measurements results in more women classified with GDM (Claver, 2020; van den Berg, 2015; Balaji, 2012).

The study aims to gain insight in the analytic quality and usefulness of the Roche Accu-Chek Inform II to screen for GDM to improve the general care of pregnant women during an OGTT. This study compares the capillary glucose values and venous glucose values (gold standard) at all the three sampling times of the OGTT in a large group of pregnant women in the Netherlands.

Study objective

The aim of this study is to determine a high level of agreement between readings obtained from the plasma levels and the Roche Accu-Chek Inform II.

Study design

During Oral Glucose Tolerance testing

Intervention

Capillary blood sampling in addition to venous sampling

Contacts

Public
Zuyderland Medisch Centrum
Jonas Ellerbrock

088-4597777
Scientific
Zuyderland Medisch Centrum
Jonas Ellerbrock

088-4597777

Eligibility criteria

Inclusion criteria

12-40 weeks pregnant

Indication for OGTT

Exclusion criteria

Unable to read informed consent in Dutch or English

Pre-gestational diabetes mellitus (type I or II)

Using glucose lowering medication (for example Metformin or Glyburide)

History of bariatric surgery with dumping in the past

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2021
Enrollment:	330
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Positive opinion

Date:	10-03-2021
Application type:	First submission

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
NTR-new	NL9308
Other	METC-Z : Z2021049

Study results