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

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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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24013

Bron
Nationaal Trial Register

Verkorte titel
POCT-SUGAR

Aandoening

Gestational Diabetes, Pregnancy

Ondersteuning

Primaire sponsor: Zuyderland Medisch Centrum
Overige ondersteuning: Not applicable

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Level of agrement between plasma levels and capillary samples.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

During Oral Glucose Tolerance testing

Onderzoeksproduct en/of interventie

Capillary blood sampling in addition to venous sampling

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

12-40 weeks pregnant

Indication for OGTT

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2021
Aantal proefpersonen:	330
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Ethische beoordeling

Positief advies

Datum:	10-03-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9308
Ander register	METC-Z : Z2021049

Resultaten