# Screening gestational diabetes: glucose curve versus oral glucose tolerance test

Published: 12-10-2021 Last updated: 04-04-2024

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

# Summary

## ID

NL-OMON51070

**Source** ToetsingOnline

**Brief title** Screening gestational diabetes

## Condition

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

### Synonym

High suger levels in pregnancy

**Research involving** Human

## **Sponsors and support**

### Primary sponsor: Albert Schweitzer Ziekenhuis

**Source(s) of monetary or material Support:** Lokaal wetenschapsfonds van het Albert Schweitzer ziekenhuis.

## Intervention

Keyword: Gestational Diabetes, Glucose curve, OGTT, Pregnancy

#### **Outcome measures**

#### **Primary outcome**

The primary objective is to compare the glucose curve with the OGTT, as a screening test for GDM, which gives the following questions: - Is there any difference in pre-prandial and postprandial capillary blood glucose values between the glucose curve and OGTT, and how are these glucose values related with the diagnosis of GDM? (paragraph 6.3.2) - What are the sensitivity and specificity of glucose curve in relation to the OGTT?

#### Secondary outcome

The secondary objective is to investigate if the predictive value of the glucose curve on perinatal outcomes after treating GDM is comparable with the predictive value of the OGTT. The hypothesis is that the glucose curve is not inferior to the OGTT in diagnosing GDM. All patients diagnosed with GDM will receive treatment, either insulin or diet only. To verify this hypothesis, we investigate the perinatal outcomes. If the glucose curve is not inferior to the OGTT, it can be expected that the perinatal complications will be equally divided in both groups. Due to increasing insulin resistance with gestation of pregnancy and multiple testing later on in pregnancy we hypothesize that we identify more GDM.

Another objective is to investigate how patients will experience the OGTT and the glucose curve, and if they have a preference.

The breakfast screenings test (BST) consist of the first two glucoses of the

glucose curve, another objective is to compare the BST and the OGTT just as

mentioned above with the glucose curve.

# **Study description**

#### **Background summary**

Gestational diabetes mellitus (GDM) is defined as any type of hyperglycaemia during pregnancy. It is known that GDM can cause more risks for perinatal complications. GDM is often asymptomatic and therefore the diagnosis is found by screening. Screening of GDM takes place when there are certain risk factors and is essential to reduce perinatal complications with treating GDM that is found by screening.

At the moment, screening strategies for GDM are under discussion. In many clinics, the oral glucose tolerance test (OGTT) is used for screening GDM. The OGTT is burdensome for most pregnant patients, as it is a time-consuming function test and can cause nausea and vomiting. A possible alternative for the OGTT is the glucose curve, but there is no evidence about the standardisation and the applicability in the diagnostic work-up of GDM. The WHO considers screening strategies for GDM a priority area for research.

The main study endpoint is to objectivy whether the glucose curve is a good alternative for the OGTT screening for GDM. Futhermore we are interested in the sensitivity in the glucose curve and the OGTT and their differences. Thereby, we study whether the glucose curve is a good alternative for the OGTT predicting perinatal complications. In addition, the patients experience regarding the glucose curve and the OGTT will be investigated.

### **Study objective**

The primary objective is to compare the glucose curve with the OGTT, as a screening test for GDM.

The secondary objective is to see if GDM treated after screening either with the glucose curve or with the OGTT, can predict perinatal complications and if there is a difference between these two groups. The breakfast screeningstest (BST) consist of the first two glucoses of the glucose curve, another objective is to compare the BST and the OGTT just as mentioned above with the glucose curve.

### Study design

This is a prospective observational single-blinded non-inferiority study. Patients who need screening for GDM will be asked to do an additional test for GDM screening. The glucose curve and the OGTT will be performed in the same week, and the results of the capillary blood glucose will be compared.

## Study burden and risks

The possible side effects of the OGTT are nausea and vomiting due to the high doses of sugar. There will be more capillary blood tests during this study compared to the routine screening.

# Contacts

**Public** Albert Schweitzer Ziekenhuis

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# **Trial sites**

# **Listed location countries**

Netherlands

# **Eligibility criteria**

## **Inclusion criteria**

Pregnant woman and one of the following risk factors, whereas screening for GDM is necessary:

o GDM in history;

o Body Mass Index (BMI) above 30 kg/m2 before pregnancy;

o An earlier child with a birth weight above 4500 gram or the 95th percentage;

o A first-degree family member with diabetes or GDM;

- o Ethnic background: African, Turkish, Hindu, Asian, Latin-American;
- o Inta-uterine death in history without a medical explanation;

o Polycystic ovarian syndrome.

# **Exclusion criteria**

All pregnant patients are screened for diabetes with random glucose at the beginning of the pregnancy before 16 weeks. Patients will be excluded if:

- Diagnosed with diabetes mellitus type 1 or type 2;
- Earlier diagnosed GDM during this pregnancy;
- Age under 18 years;

- Received bariatric surgery in their medical history, as this is a contra-indication for the OGTT.

Patients will be excluded if they are unable to give written consent or when there is no proper understanding of Dutch or English.

# Study design

## Design

Study type: Observational invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

## Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-01-2022
Enrollment:	158
Туре:	Anticipated

# **Ethics review**

Approved WMO	
Date:	12-10-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

# **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 CCMO ID NL76738.078.21