

# Comparison of different diagnostic tests for gestational diabetes mellitus between 24 - 28 weeks of pregnancy in high risk groups.

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To compare the burden for pregnant women and diagnostic capabilities of the oral glucose tolerance test (75g and 50g) and blood glucose samples during the day.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Glucose metabolism disorders (incl diabetes mellitus)
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON32928

### Source

ToetsingOnline

### Brief title

DIGRADIT

### Condition

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

### Synonym

gestational diabetes

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Medisch Centrum Leeuwarden

**Source(s) of monetary or material Support:** MCL

## **Intervention**

**Keyword:** Diagnostic tests, Gestational diabetes gravidarum, oral glucose challenge test

## **Outcome measures**

### **Primary outcome**

Blood glucose samples in venous plasma.

The burden of the diagnostic tests, measured by a questionnaire for pregnant women.

### **Secondary outcome**

None.

## **Study description**

### **Background summary**

According to the Dutch societies of Obstetrics and Gynaecology and Internal Medicine, the oral glucose tolerance test (75 g) is the most accurate diagnostic test for gestational diabetes. Pregnant women who are at risk to acquire gestational diabetes must receive this test at 24-28 weeks of gestation. Because of its practical limitations including time and unpleasant side effects from drinking the glucose solution gynaecologists are reluctant to use this test. We compare the side effects and diagnostic capabilities of the two oral glucose tolerance tests (75g and 50g) and blood glucose samples during the day.

### **Study objective**

To compare the burden for pregnant women and diagnostic capabilities of the oral glucose tolerance test (75g and 50g) and blood glucose samples during the day.

### **Study design**

Observational study with invasive measurements partly randomized.

## Study burden and risks

The oral glucose tolerance test (50g) and blood glucose samples during one day.

## Contacts

### Public

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8901 BR Leeuwarden  
NL

### Scientific

Medisch Centrum Leeuwarden

postbus 888  
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NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)  
Elderly (65 years and older)

### Inclusion criteria

large for gestational age (> p95), Polyhydramnion (AFI> 24 cm), Diabetes mellitus in the family, history of gestational diabetes, macrosomia (>p97,5) and/of unexplained intra-uterine death. body mass index> 27 kg/m<sup>2</sup>, mediterranean or hindoestane ethnicity.

## Exclusion criteria

History of diabetes mellitus,  
random glucose > 7.8mmol/l before 20 weeks of pregnancy.

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-10-2009
Enrollment:	200
Type:	Actual

### Medical products/devices used

Registration:	No
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## Ethics review

Approved WMO	
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

## 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	NL26812.099.09