Flash Glucose Monitoring: an alternative screening method for Gestational Diabetes Mellitus?

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

Summary

ID

NL-OMON55968

Source
ToetsingOnline

Brief title
FGM: an alternative screening method for GDM

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Maternal complications of pregnancy

Synonym
GDM, gestational diabetes

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Flash Glucose Monitoring, Gestational Diabetes Mellitus, Oral Glucose Tollerance Test (OGTT)

Outcome measures

Primary outcome

Outcomes:

- Gestational age at start FGM in weeks + days

- Time above target range (>7.8 mmol/l) in percent. Where >1% is abnormal.

- Active sensor in percent minimum 80% active sensor needed for reliable image

- FGM diagnosis GDM yes/no

- Gestational age at taking OGTT, in weeks + days

- OGTT result fasting capillary glucose in mmol/l

- Result OGTT two-hour capillary glucose value in mmol/l

- OGTT diagnosis GDM yes/no

Secondary outcome

Patient characteristics

- Age in years at first antenatal check-up

- BMI at first antenatal check-up in kg/m2

- How many pregnancy

- À terme date

- Indication OGTT

- Evidencio score in percent rounded to one decimal point. This is a prediction

model which calculates the pregnant person's risk of developing GDM and is

calculated in the first trimester of pregnancy

Study description

Background summary

Diabetes gravidarum (GDM), also known as gestational diabetes, is a disorder of carbohydrate metabolism diagnosed in the second or third trimester of pregnancy, where no diabetes mellitus (DM) was present before pregnancy. GDM usually causes no symptoms but is related to perinatal and maternal complications such as macrosomia, shoulder dystocia, neonatal hypoglycaemia and neonatal hyperbilirubinaemia. In the longer term, women with pervasive GDM have a 10-fold higher risk of developing type 2 diabetes mellitus. The prevalence of GDM is increasing worldwide. Treatment of GDM focuses primarily on dietary interventions with glucose monitoring and advice to exercise sufficiently. GDM can be treated in 70-85% of patients with diet and exercise advice. If this is insufficiently effective within two weeks, treatment with insulin therapy is advised.
GDM is diagnosed with the gold standard the oral glucose tolerance test (OGTT). This involves taking blood sober after which the woman has to drink 75 grams of pure glucose. Another blood draw follows after two hours. The OGTT is taken if the woman meets the risk factors for developing GDM. These risk factors are according to the Dutch Society for Obstetrics and Gynaecology (NVOG) guideline diabetes and pregnancy; GDM in the past history, body mass index (BMI) above 30 kg/m2 before pregnancy, previous child with a birth weight above 4500 grams or growth curve above the 95th percentile, first-degree relative with diabetes mellitus (DM), certain ethnic groups (South Asians, Hindus, Afro-Caribbean, Middle Eastern, Moroccan and Egyptian), unexplained intra uterine foetal death in the past history and polycystic ovarian syndrome (PCOS). Research shows that 47% of women experience drinking 75g of glucose drink as (very) unpleasant, 48% experience mild to moderate pain during blood sampling and 48% have increased anxiety feelings where it is unclear whether these are anxiety feelings for the test and blood sampling or for the results, 18% find being sober unpleasant, drinking the glucose drink is perceived as the most difficult part. Of the women, 10% vomit when drinking the oral glucose drink. Alternatives to screening for GDM with, for example, a glucose day curve or random glucose value is insufficiently sensitive and specific. The Flash Glucose Sensor (FGM) is a relatively new way to measure glucose in people with DM. The FGM is approved for use in pregnancy. The use of FGM leads to an improvement in quality of life in people with DM and these people are faster and better regulated. In studies in pregnant women with diabetes mellitus type 1, 2 or GDM, we see higher patient satisfaction, the FGM is more sensitive in detecting hypoglycaemias and there was greater understanding of glucose variability compared to daily curves. Of the women, 100% would choose the FGM over

capillary glucose measurements during the treatment of GDM.
The OGTT is the gold standard in screening for GDM, but is considered burdensome by many women. The FGM leads to better and faster regulation in DM and more insight into glucose variability. However, it is unknown whether the FGM could be used in screening for GDM and what the sensitivity, specificity, positive predictive value and negative predictive value are of the FGM compared to the OGTT.

Study objective

The aim of this prospective diagnostic validation study (pilot study) is to establish some clinimetric properties of FGM (sensitivity, specificity, positive predictive value and negative predictive value of the FGM compared to the OGTT). If FGM can be used as a screening tool, then there is no need to do an OGTT, which women find annoying. In addition, due to the immediate feedback of glucose values, the instrument can be used in education and treatment, potentially making the treatment of GDM more efficient and patient-friendly.

Research questions:
What are the sensitivity and specificity of FGM in screening for GDM in the second trimester of pregnancy?
What are the positive and negative predictive values of FGM in screening for GDM in the second trimester of pregnancy?

Study design

Prospective diagnostic validation study (pilot study) conducted in women in the second trimester of pregnancy

Intervention

As part of diagnostic research, an FGM will be placed in addition to the standard OGTT (placement is an act). The subject will then scan the sensor every 8 hours for 7 days (there may be more than 8 hours in between during the night).

Study burden and risks

The pregnant woman wears the sensor on the back of the upper arm, which is attached with a plaster. Skin reaction at the patch site may occur, in practice we rarely see this, with redness and itching being the most common.
The pregnant woman sees the scanned glucose values immediately, this could potentially cause uncertainty.

The OGTT and associated blood sampling are performed according to current

guidelines and are not an additional burden as part of this study

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Adult woman between 24 and 28 weeks of pregnancy who is eligible for an OGTT in primary obstetric care according to the guideline of the Dutch Society of Obstetrics & Gynaecology

Exclusion criteria

Diabetes mellitus in history

Pregnant women in 2nd and 3rd line obstetric/gynaecological care.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	25-10-2023
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	20-09-2023
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL83953.091.23