Continuous glucose monitoring versus self-monitoring of blood glucose in women with gestational diabetes mellitus

Published: 08-12-2015
Last updated: 19-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Diabetic complications
Study type	Observational invasive

Summary

ID

NL-OMON42812

Source
ToetsingOnline

Brief title
The SensoCap Trial

Condition

- Diabetic complications
- Maternal complications of pregnancy

Synonym
diabetes in pregnancy, Gestational diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Maasstadziekenhuis
Source(s) of monetary or material Support: Medtronic BV

Intervention

Keyword: CGMS, continue glucose monitoring, gestational diabetes mellitus, glucose

Outcome measures

Primary outcome

Primary objective: To assess the hyperglycemic episodes (fasting glucose >= 5.3 mmol/L and 6.7 mmol/l the rest of the day) detected by the CGMS when the SMBG is normal in a 24 hour period.

Secondary outcome

1. The secondary endpoint is mean total time of hyperglycemia (glucose>= 5.3 mmol/L fasting and >= 6.7 mmol/L) defined in minutes/day, that is detected by the CGMS compared to standard SMBG (7 measurements in a day).

2. Is there a difference in glycaemic control (data is binary: hyperglycaemia or no hyperglycaemia) between day 2 (SMBG) and day 3 (no SMBG) of the monitoring period?

Background (2): We are curious what the effect of SMBG is on the glucose regulation. Is it so that on the day of the SMBG, women adhere better to the diet and on the other days less or not? Possibly suggesting that hyperglycaemia could prevail unnoticed.

Study description

Background summary

Gestational Diabetes Mellitus (GDM) is a frequent pregnancy complication and associated with complications for mother and child. Current management consists of dietary intervention and if necessary additional insulin therapy. Treatment decisions regarding initiation of insulin treatment are based on self-monitoring of blood glucose (SMBG). The optimal frequency of glucose measurements remains to be elucidated. The problem with SMBG is that it gives single measurements and no longitudinal glucose profile. Continuous Glucose Monitoring (CGM) provides information regarding the fluctuations of glucose during the day. In this study we aim to evaluate the detection rate of hyperglycemia with a CGMS (continuous glucose monitoring system) compared to standard SMBG.

Study objective

The hypothesis is that SMBG underestimates the number of hyperglycaemic episodes in women with gestational diabetes mellitus.
The aim of this study is to evaluate if CGMS detects hyperglycaemia when the standard SMBG day curve is normal.

Study design

It is a one-year prospective observational study. The setting is outpatient. Pregnant women with GDM are eligible to participate. Subjects will be informed about the study during their regular visit to the diabetology outpatient clinic in het Maasstad Hospital.

Patients can enrol in the study at any time before 36 weeks of gestation. All subjects participating in the study will receive the CGMS (Medtronic® Minimed, Northridge, Ca, USA), regardless of their treatment for GDM (diet or insulin). The CGMS will monitor at 20, 30 and 36 weeks of gestation, depending on the term of pregnancy in which they enter the study. Each monitoring period consists of 72-hours and requires two visits to our centre. Subjects will visit our centre a minimum of two times and a maximum of 6 times, depending on the term of pregnancy in which they enter the study. During each visit the CMG system I-Pro® is either inserted into the subject or removed and instructions are given.

Timetable of visits:

Gestational age (weeks)
Week 20 Visit 1 (day 1) Visit 2 (day 4)

Inserting CGMS Removing CGMS
Week 30 Visit 3 (day 1) Visit 4 (day 4)
Inserting CGMS Removing CGMS
Week 36 Visit 5 (day 1) Visit 6 (day 4)
Inserting CGMS Removing CGMS

Each visit is the start of a 72-hour consecutive CGM period. Subjects need to keep a diary of their intake during the monitoring period. In total subjects will wear the CGMS intermittently for the duration of 9 days (maximum) during pregnancy.

Study burden and risks

Subjects visit our centre a minimum of two and a maximum of six times during pregnancy. Each visit the CGMS will be inserted/removed from the subject. During the 72-hour monitoring period, the subject is required to measure blood glucose three times a day to calibrate the device (day 1 and 3). It is standard care to do a 7 point glucose day curve once a week (day 2). In total a maximum of 6 extra blood glucose measurements are required per three day (72 hour) monitoring period. Subjects are also required to fill in a diary of their dietary intake during the monitoring periods. Potential discomfort could be in the form of a local reaction (pain or hematoma) or skin rash due to the CGMS.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Women who are >=18 years old, diagnosed with GDM, < 36 weeks of gestation, are able to communicate and read in Dutch.

Exclusion criteria

no singleton pregnancy judged by ultrasonography, diagnosis of diabetes mellitus before the current pregnancy.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-03-2016
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Medtronic MiniMed (iPro)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	08-12-2015
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (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	ID
CCMO	NL55203.101.15

Study results

Date completed:	27-03-2017
Actual enrolment:	31