The value of Flash Glucose Monitoring in diagnosing gestational diabetes mellitus in pregnant women after bariatric surgery.

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

Summary

ID

NL-OMON49989

Source
ToetsingOnline

Brief title
DIAFREE

Condition

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

Synonym
pregnancy induced diabetes mellitus, Sugar disease

Research involving
Human

Sponsors and support

Primary sponsor: Elisabeth-Tweesteden ziekenhuis
Source(s) of monetary or material Support: transformatiegelden binnen ETZ.

Intervention

Keyword: Bariatric surgery, Flash Glucose Monitoring, Gestational diabetes mellitus

Outcome measures

Primary outcome

* Glucose variation

* Average glucose

* Time in range

Secondary outcome

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Study description

Background summary

Obesity is a global and fast growing health problem. The number of obese women has increased 5-fold since 1975. One of the treatments for obesity is bariatric surgery. The desire to have children is among the top 5 reasons for Dutch women to request this type of treatment. Indeed, the chance of pregnancy is increased 58% after bariatric surgery.

The outcomes of pregnancy are greatly improved after bariatric surgery. There are nonetheless maternal and fetal risks, such as alimentary deficiencies, dumping syndrome, and an increased risk of the child being small for gestational age (SGA). The risk of gestational diabetes mellitus (GDM) is smaller for women after bariatric surgery If compared to obese women who did not undergo this procedure, but is still higher if compared to the normal population. It therefore remains important to perform screening for GDM in women who became pregnant after bariatric surgery.

The gold standard for diagnosing gestation diabetes is the oral glucose tolerance test (OGTT). However, this test is contraindicated in women after

bariatric surgery due to the high risk of symptomatic hypoglycaemia. Instead a 4-points self-monitoring blood glucose (SMBG) profile is acquired on a single day, comprising a fasting glucose and glucose measurements 1 hour after the meal. The SMBG profile is abnormal if one of the values exceeds a predefined limit (5.3 mmol/l for fasting glucose, 7.8 mmol/l for postprandial glucose). The reliability of this method for diagnosing GDM is unknown.

Recently the FreeStyle Libre (FSL) has become widely available as a relatively inexpensive method to continuously measure interstitial glucose levels. It is able to produce reliable 24-hour glucose patterns and trends.

Study objective

The current study will investigate whether the FSL can be used to establish the diagnosis GDM in women who became pregnant after bariatric surgery. To accomplish this, first it will be necessary to gain insight into the continuous glucose pattern of women, with and without gestational diabetes, who are pregnant but did not undergo bariatric surgery.

Study design

This study is a cross-sectional pilot study and will take place in the Elisabeth TweeSteden hospital in Tilburg, the Netherlands. The study contains 4 research groups that each will include 10 subjects:
1) pregnant women without GDM, i.e. normal OGTT;
2) pregnant women with GDM i.e. abnormal OGTT;
3) pregnant women with a history of bariatric surgery;
4) fertile non-pregnant women with a history of bariatric surgery.
In groups 1 to 3, the OGTT or 4-points SMBG will take place according to protocol in the 25th week of pregnancy. Directly after this test is performed, a research period of 7 days will start in which the FSL will be worn by the subject to generate a continuous glucose pattern. Data will be collected in Libreview. Directly afterwards, if warranted, treatment for GDM will start according to hospital guidelines. For group 4, a similar research period of 7 days will take place after pregnancy and diabetes mellitus are excluded. These women will also perform a 4-points SMBG on a single day during this 7 day period.

Analysis
Diagnostic FSL-based criteria for GDM will be sought by comparing continuous glucose patterns between women with and without GDM (group 1 and 2). These criteria will be applied to pregnant women after bariatric surgery (group 3) to establish an FSL-based diagnosis of GDM. The reliability of the devised criteria will be assessed by analysing the glucose patterns of non-pregnant women after bariatric surgery (group 4) and by comparing to the outcomes of the 4-points SMBG in both group 3 and 4.

Study burden and risks

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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

Singleton intrauterine pregnancy
Indication for oral glucose tolerance test or 4-point glucose profile
Bariatric surgery >1 year ago
Group BSP- (not pregnant and age between 18-40 years; bariatric surgery > 1 year ago; stable weight)

Exclusion criteria

Pre-existent diabetes mellitus
Use of medication that influences insulin or glucose concentration
Pregnancy <1 year after bariatric surgery

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-02-2021
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	FreeStyle Libre
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	28-10-2020
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

Approved WMO Date:	11-03-2021
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL74824.028.20