Hypoglycemia in post-bariatric vs. non-bariatric pregnancy: incidence and effects on fetal growth

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Determine the number of hypoglycemic events (fasting and postprandial) during post-bariatric pregnancies compared to non-bariatric pregnancies (with obese and healthy BMI) using continuous glucose monitoring and its effects on fetal growth.

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

Summary

ID

NL-OMON56907

Source
ToetsingOnline

Brief title
Hypo-baby

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Foetal complications
- Gastrointestinal therapeutic procedures

Synonym
hypoglycemia, low blood sugar

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden

Source(s) of monetary or material Support: Dexcom,Medisch Centrum Leeuwarden

Intervention

Keyword: Continuous glucose monitoring, Hypoglycemia, Metabolic-bariatric surgery, Pregnancy

Outcome measures

Primary outcome

The main endpoint is the number of hypoglycemic events (fasting and postprandial) during post-bariatric pregnancies and non-bariatric pregnancies (with obese and healthy BMI).

Secondary outcome

The secondary study parameters are neonatal birthweight, gestational weight gain, placental weight and histology, micronutrient deficiency, and nu number of hyperglycemic events. Other parameters are data from the patient file (age, ethnicity, comorbidities, pre-bariatric weight).

Study description

Background summary

Current research suggests hypoglycemia is common in pregnancies after metabolic-bariatric surgery (MBS) and may contribute to fetal growth (FG) restrictions. However, the incidence of hypoglycemia is highly variable between studies, and evidence for its effects on FG is limited. Previous research into the extent in which hypoglycemia is responsible for FG restrictions after MBS often does not determine whether the incidence of hypoglycemia differs between trimesters, nor investigate other factors that might contribute to FG restrictions, such as gestational weight gain (GWG), placental quality, and post-BS micronutrient- and protein deficiencies. Additionally, more research into the incidence of hyperglycemia during pregnancy after MBS is important, as research suggests that it is increased in pregnancy after MBS.

Study objective

Determine the number of hypoglycemic events (fasting and postprandial) during post-bariatric pregnancies compared to non-bariatric pregnancies (with obese and healthy BMI) using continuous glucose monitoring and its effects on fetal growth.

Study design

This study is a prospective observational study, using continuous glucose monitoring.

Study burden and risks

The burden for the subjects consists of the following: During each trimester of the pregnancy (at 12-14, 24 and 34 weeks), continuous glucose monitoring (CGM) will be done for 7 days, a blood sample will be taken, and the patient is weighted. Each subject will have 3 on site visits to place the CGM device. During the CGM, patients will fill out a patient diary on symptoms of hypoglycemia, food intake and daily activities. After the birth, the palcenta is weighted. If the patient gives birth in the MCL, the placenta is send in for histological analysis. The risk for the subjects is low. During this study, we will determine the incidence of hypoglycemia in post-bariatric pregnancies and its potential effects on FG. The findings of the study can help us better our understanding of the effects of hypoglycemia on FG and thereby increase the number of uncomplicated pregnancies after bariatric surgery.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria: Pregnant, either after metabolic-bariatric surgery (Roux-en-Y gastric bypass or One anastomosis gastric bypass performed at CON, MCL with pre-surgery BMI >40, and post-BS total weight loss (TWL) of >20%), or without metabolic-bariatric surgery with BMI >40 or BMI between 18.5-24.9. At the time of inclusion, the subject must be between 6-10 weeks pregnant.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Diagnosis with type 1 or type 2 diabetes before the pregnancy, or diagnosis with type 1 or type 2 diabetes or GDM before the BS.
- Diagnosis with severe psychiatric or medical comorbidities known to potentially affect fetal growth (e.g. severe depression, lupus, chronic kidney disease).
- Continued smoking, alcohol consumption, or substance use throughout the pregnancy.
- Allergy for plasters.
- Multiple pregnancy.
- Pregnancy less than 12 months after bariatric surgery.
- Post-bariatric total weight loss of <20%

Study design

Design

Study type: Observational invasive

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2024
Enrollment:	174
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	30-07-2024
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	NL86830.099.24