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Self-monitoring of blood sugar level in mild gestational diabetes: weekly compared to every 2 weeks

Submission date
22/03/2022

Recruitment status
No longer recruiting

Registration date
25/03/2022

Overall study status
Completed

Last Edited
22/05/2023

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Self-monitoring of blood glucose (SMBG) by finger-prick blood testing usually four times per day is the recommended method to monitor blood sugar control in women with diabetes of pregnancy (gestational diabetes mellitus [GDM]). In women with GDM whose blood sugar is well controlled on diet alone, the optimum frequency of SMBG to achieve the best blood sugar control is not established. University Malaya Medical Centre advised for SMBG not more frequently than weekly for women with GDM. The aim of this study is to compare 1 day of four-point blood sugar monitoring every week to 1 day every 2 weeks, using glycated haemoglobin (HbA1c) level as the marker of blood sugar control, which is an integrated measure of the average blood glucose level over the last 2-3 months.

Who can participate?
Women aged 18 years and over with GDM, gestational age 24-32 weeks, and whose GDM is controlled with diet and lifestyle modification alone

What does the study involve?
A blood sample (3 ml) will be taken for HbA1c testing at recruitment. Participants will be then randomly allocated into either once every week or once every 2 weeks four-point blood sugar monitoring. Participants will be taught how to use the glucometer and provided with a personal glucometer, test strips, and stylets free of charge. The participants are then expected to monitor their blood glucose at home as instructed and record all glucometer readings in the diary provided. Standard pregnancy and delivery care will be provided. Participants will be followed up in the antenatal clinic every 1-4 weeks depending on their condition by an investigator. The participants should continue their diet and exercise as advised. If their blood sugar profile is high during follow up, medical management will be started and SMBG intensified. At 36 weeks gestation, another blood sample (3 ml) will be obtained for the second HbA1c test. The cost for the HbA1c test will be covered. The glucometer will be returned to the investigator at the end of the study following hospital discharge for delivery. All other aspects of pregnancy and delivery care is as the usual standard for GDM.

What are the possible benefits and risks of participating?
Participants allocated to weekly SMBG will need to prick their fingers 16 times every 4 weeks compared with eight times in two weekly SMBG. There may be pain, bleeding and risk of infection due to finger pricks and venous blood taking. More intensive monitoring can result in intervention which may prove to be unnecessary. Less intensive monitoring can result in a short delay in starting treatment to control blood glucose. Participants should not expect any other benefit as it is not proven whether more frequent monitoring is associated with better glucose levels or pregnancy outcomes.

Where is the study run from?
University Malaya Medical Centre (Malaysia)

When is the study starting and how long is it expected to run for?
October 2021 to February 2023

Who is funding the study?
University Malaya Medical Centre (Malaysia)

Who is the main contact?
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Additional identifiers

Protocol serial number
20211112-10772

Study information

Scientific Title
Weekly compared to two weekly self-monitoring of blood glucose in mild gestational diabetes: a randomized controlled trial

Acronym
SMBGinGDM

Study objectives
It is hypothesized that four point per day self-monitoring of blood glucose every 2 weeks compared to every week is non-inferior in maintaining glycated haemoglobin (HbA1C) level from enrolment to 36 weeks gestation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/03/2022, Medical Research Ethics Committee of University of Malaya Medical Centre (Lembah Pantai, 59100 Kuala Lumpur, Malaysia; +60 (0)3 7949 3209; iresearch@ummc.edu.my), ref: MREC ID:20211112-10772

Primary study design
Interventional

Study design
Randomized controlled clinical intervention trial with an open-label design

Study type(s)
Other

Health condition(s) or problem(s) studied
Mild gestational diabetes

Interventions
Participants will be randomized in a 1:1 ratio to weekly or two weekly self-monitoring of blood glucose (SMBG):
1. One day per week of four-point (fasting/prebreakfast and 2 hours after breakfast, lunch and dinner) blood sugar profile with self-monitoring of blood glucose alternately, on a weekday and a weekend day until delivery
2. One day every 2 weeks of four-point (fasting/prebreakfast and 2 hours after breakfast, lunch and dinner) blood sugar profile with self-monitoring of blood glucose alternately, on a weekday and a weekend day until delivery

The randomization sequence will be generated in random blocks of 4 or 8 by a co-investigator who is not involved in recruitment. Numbered, sealed and opaque envelopes will be used with the lowest-numbered envelope remaining assigned to the latest recruit.

All participants will be provided standard care of dietary, lifestyle and weight gain advice and antenatal follow-up and delivery management for gestational diabetes for each arm from recruitment until delivery.

Intervention Type
Other

Primary outcome(s)
Blood sugar control measured using glycated haemoglobin (HbA1c) level at enrolment to 36 weeks gestation

Key secondary outcome(s)

1. Maternal outcomes assessed by reviewing patient's notes after delivery:
1.1. Gestational age at delivery
1.2. Maternal weight at delivery
1.3. Maternal weight gain
1.4. Need for antiglycemic agent (e.g., metformin, insulin)
1.5. Induction of labor
1.6. Mode of delivery
1.7. Epidural analgesia for labor
1.8. Indication for cesarean delivery
1.9. Delivery blood loss
1.10. Shoulder dystocia
1.11. Third- or fourth-degree tear
1.12. Placenta weight
2. Neonatal outcomes assessed by reviewing patient's and baby's notes after delivery:
2.1. Birth weight (low birth weight <2.5 kg; macrosomia >3.5 kg)
2.2. Umbilical cord arterial pH and base excess at birth
2.3. Apgar score at 1 and 5 minutes
2.4. Neonatal hypoglycemia
2.5. Neonatal birth injury (e.g., Erbs palsy, bone fracture, cephalhematoma etc)
2.6. Special care nursery/neonatal intensive care unit admission and indication

Completion date
09/02/2023

Eligibility

Key inclusion criteria
1. 75-g oral glucose tolerance test in pregnancy with fasting ≥ 5.1 mmol/l and/or 2-hour ≥ 8.5 mmol/l
2. Gestational age 24-32 weeks at recruitment
3. Aged ≥18 years old
3. Singleton viable pregnancy
4. Normal four-point blood sugar profile from self-monitoring of blood glucose in the preceding 2 weeks (fasting/pre-prandial ≤ 5.3, post-prandial 1 hour ≤ 7.8 or post-prandial 2 hours ≤ 6.7 mmol/l)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Total final enrolment
104

Key exclusion criteria
1. Anti-glycemic drug treatment
2. Prepregnancy hyperglycaemia (type 1 or 2 diabetes, impaired glucose tolerance or fasting glycaemia)
3. 75-g oral glucose tolerance test in pregnancy fasting plasma glucose ≥ 7.0 and/or the 2-hour level ≥ 11.1 mmol/l
4. Anaemia (haemoglobin level of <8 g/dl)
5. Medical condition likely to result in delivery before 36 weeks gestation

Date of first enrolment
12/04/2022

Date of final enrolment
15/11/2022

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Centre (UMMC)
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Sponsor information

Organisation
University Malaya Medical Centre

ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Malaya Medical Centre

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	18/05/2023	22/05/2023	Yes	No