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Self-monitoring of blood glucose of three days compared to one day per week in mild gestational diabetes

Submission date
03/01/2018

Recruitment status
No longer recruiting

Registration date
23/01/2018

Overall study status
Completed

Last Edited
27/02/2023

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
Gestational diabetes mellitus (GDM) is high blood sugar in response to carbohydrate intake which is first detected during pregnancy. It is estimated that 16% of live births in 2015 were affected by high blood sugar with 85% due to GDM. Good control of blood sugar in GDM reduces the risk of adverse pregnancy outcomes. Self-monitoring of blood glucose (SMBG) with a personal glucose meter using pin prick blood from a finger is recommended for women with diabetes during pregnancy. There is a lack of data on the needed frequency for SMBG in GDM. A study that compared daily 4-point SMBG (blood glucose tests before meals and before bed) with weekly single-point fasting office-based testing finds a reduction in the incidence of big baby (birth weight of 4 kg or more), large for gestational age infants and less maternal weight gain with the 4-point every day SMBG. The Malaysian Ministry of Health Perinatal Care Manual recommends SMBG 4 points per day as infrequently as one day out of every 4 weeks for GDM patients on diet and lifestyle control only and only one day out of every 2 weekly if on insulin. With diet and lifestyle advice, GDM cases can be adequately controlled with only about 20% needing drug treatment. Hence many women with GDM have normal blood sugar profiles through pregnancy, bringing into question the need for frequent blood testing on a daily basis. On the other hand, the discipline, positive feedback and validation from more frequent SMBG that are within normal range may contribute to a stronger adherence to good diet and lifestyle choice, resulting in lower glucose levels through pregnancy. The glycated haemoglobin (HbA1c) level typically reflects average blood glucose level over the preceding 2-3 months. Higher HbA1c toward the end of pregnancy is associated with adverse pregnancy outcomes. The aim of this study is to compare 4-point SMBG on three days per week compared to one day per week, to see whether it reduces the patients' HbA1c levels.

Who can participate?
Women aged 18 to 45 with a single pregnancy and confirmed GDM

What does the study involve?
Participants are randomly allocated to SMBG using a personal blood glucose monitor at 4 timepoints per day (i.e. when still fasted before breakfast, and 2 hours after breakfast, lunch and

dinner) for either: 3 days per week (on 2 week days and 1 weekend day each week) or 1 day per week (on a week day or a weekend day on alternate weeks). Participants are followed up until delivery. HbA1c levels are measured using a blood sample at the start of the study and at 36 weeks.

What are the possible benefits and risks of participating?
Participants should not expect any benefit as it is not proven whether more frequent monitoring than on a weekly basis leads to better glucose levels or pregnancy outcomes. The possible disadvantages are the participants allocated to 3 days per week SMBG will need to prick their fingers 12 times a week compared with 4 times a week for the other group. More intensive monitoring can result in intervention which may prove to be unnecessary.

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?
January 2018 to December 2018

Who is funding the study?
Department of Obstetrics and Gynaecology Support for Research Funding (Malaysia)

Who is the main contact?
Dr Ahmad Firdzaus Mohd Noor

Contact information

Type(s)
Scientific

Contact name
Dr Ahmad Firdzaus Mohd Noor

Contact details
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Seksyen 4 Tambahan
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43650

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2017104-5626

Study information

Scientific Title
Self-monitoring of blood glucose of three days compared to one day per week in mild gestational diabetes: a randomised trial

Acronym
SMBG-GDM

Study objectives
Three days vs one day per week (4-point per day) of self monitoring of blood glucose in mild gestational diabetes will lower HbA1c level by 0.2% by 36 weeks gestation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Research Ethics Committee, University Malaya Medical Centre, 29/11/2017, ref: MREC ID NO: 2017104-5626

Study design
Open-label randomised trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Gestational diabetes

Interventions
Randomisation sequence will be generated in random blocks of 4 or 8 using a random number generator by a co-investigator who is not involved in recruitment. Participants will be randomised to self-monitoring of blood glucose using a personal blood glucose monitor 4 time points per day (i.e. when still fasted before breakfast, 2 hours after breakfast, lunch and dinner) for either:
1. 3 days per week (on 2 week days and 1 weekend day each week)
2. 1 day per week (on a week day or a weekend day on alternate weeks)

Patients will be under intervention and follow up from recruitment and until delivery.

Intervention Type
Device

Primary outcome measure
HbA1c level, measured using blood sample taken and sent to haematology labarotory in UMMC at recruitment and at 36 weeks

Secondary outcome measures
1. Drug treatment (e.g. metformin, insulin) during follow up
2. Pregnancy induced hypertension (BP ≥ 140 sys or 90 diastolic on 2 occasions prior to labour > 6 hours apart) during follow up
3. Gestational age at delivery
4. Induction of labor with indication
5. Epidural analgesia in labour
6. Mode of delivery:
6.1. Spontaneous vertex delivery
6.2. Instrumental delivery
6.3. Caesarean section with indication
7. Delivery estimated blood loss (major primary postpartum hemorrhage > 1000 ml)
8. Third/fourth degree tear
9. Placenta weight
10. Birth weight
11. Umbilical cord arterial pH at birth
12. Apgar score at 1st and 5th minutes
13. Special care nursery/neonatal intensive care unit admission during birth admission, indications of admission

3 to 13: the outcomes will be measured after delivery

Overall study start date
01/01/2018

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Aged 18 to 45
2. Singleton pregnancy
3. Gestational age at recruitment 20-30 weeks
4. Confirmed GDM: Fasting plasma glucose ≥ 5.1 mmol/L and/or the 2-hour ≥ 7.8 mmol/L by 75g OGTT ≥ 16 weeks of pregnancy
5. Normal 4-point blood sugar profile (BSP) in the preceding 2 weeks: fasting/pre-prandial ≤ 5.3, post prandial 1 hour of ≤ 7.8 or post prandial 2 hours of ≤ 6.7 mmol/L
6. Not on any hypoglycaemic drug treatment

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
106

Total final enrolment
106

Key exclusion criteria
1. History of prepregnant hyperglycaemia (type 2 diabetes, impaired glucose tolerance or fasting glycaemia)
2. Fasting plasma glucose ≥ 7.0 and/or the 2-hour level ≥ 11.1 mmol/L by 75g OGTT
3. Haemoglobin level of < 8
4. Medical condition likely to result in delivery before 36 weeks gestation
5. Planning to deliver in different hospital from UMMC

Date of first enrolment
02/02/2018

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Centre
Lembah Pantai
Kuala Lumpur
Malaysia
59100

Sponsor information

Organisation
University Malaya Medical Centre

Sponsor details
Lembah Pantai
Wilayah Persekutuan, Kuala Lumpur
Malaysia
59100

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Department of Obstetrics and Gynaecology Support for Research Funding

Results and Publications

Publication and dissemination plan
The study protocol and statistical analysis plan are available on request. Planned publication of the study results in a peer reviewed journal.

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Professor Dr Tan Peng Chiong (pctan@um.edu.my). The data will become available after 2 years and it is subject to the approval of the ethics committee.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		29/06/2022	27/02/2023	Yes	No