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Intermittent glucose monitoring for the management of gestational diabetes mellitus

Submission date
14/09/2022

Recruitment status
No longer recruiting

Registration date
07/11/2022

Overall study status
Completed

Last Edited
21/02/2024

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Gestational diabetes mellitus (GDM) is high blood sugar, developed during pregnancy. It affects approximately 10% (70,000) of UK pregnancies yearly. GDM can cause: 1. large babies (less safe to deliver), 2. early (pre-term) birth, 3. Caesarean section, 4. baby needing intensive care, 5. baby death, and 6. future obesity-related problems for the baby. These risks are costly for the NHS. Importantly, they can be reduced by controlling blood sugar during pregnancy. The usual care for monitoring blood sugars in GDM is “finger-prick” testing. However, using an intermittently-scanned continuous glucose monitor called "Flash", such as Flash glucose monitoring with the FreeStyle Libre 2 sensor, could be better. A Flash glucose monitor is continuously worn on the arm, just under the skin, and scanned with a Smartphone/reader to efficiently and consistently see accurate sugar levels. Blood sugar results guide women and help their doctors select appropriate treatment.
Studies show continuous blood sugar monitoring for pregnant women with type 1 (pre-existing) diabetes reduces pregnancy complications and saves money compared with “finger-prick” testing. No one has investigated whether Flash devices could make pregnancy safer for women with GDM and their babies and save NHS costs. This study aims to determine if it’s possible to carry out a large-scale study to see if wearing a continuous blood sugar monitor improves mothers’ and babies’ health in women with GDM.

Who can participate?
Pregnant women with GDM and high blood sugar levels, who have been offered medication to help manage their blood sugars.

What does the study involve?
Participants will be randomly allocated to use “finger-pricking” (usual care) or a Flash monitor. The study aims to evaluate how many:
1. Agree to take part (be recruited) and randomised
2. Use Flash correctly
3. Complete self-reported assessments
4. Whether medical/cost information can be collected to assess the effect of Flash on mother and baby health and cost-saving

Interviews will be conducted to see if:
1. Flash is acceptable, easy to use, its advantages/challenges, and whether this varies between socio-demographic groups
2. Participants were happy being randomised to use “finger-pricking” or Flash
In addition, we will interview staff (Doctors/ nurses/ midwives) to see if Flash was helpful for managing GDM.

Patient and public involvement:
Our patient and public involvement (PPI) group were confident this research could improve GDM management and pregnancy experience, including mental well-being.

The PPI work led to part of the study being redesigned to focus on the burden of different management techniques and has informed our self-reported outcome measures, to help understand whether women have better/worse experiences of blood sugar monitoring using Flash. Our group will help develop study documentation and inclusive recruitment /communication/dissemination strategies, help produce the final write-up of reports/papers and guide the development of future projects stemming from this research. Group members will form part of our Study Steering Committee, ensuring the continuity of the patient voice.

What are the possible benefits and risks of participating?
Taking part in RECOGNISE may help some women to better manage blood sugars during pregnancy and will help the design of a large-scale study that will follow RECOGNISE. Possible risks of participation include bruising and mild skin irritation from blood glucose monitoring.

Where is the study run from?
North Bristol NHS Trust, Southmead Hospital (UK)

When is the study starting and how long is it expected to run for?
March 2022 to July 2024

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Abi Loose (Trial Manager) (UK)
abi.loose@nbt.nhs.uk

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
312370

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number
IRAS 312370, CPMS 53531, (sponsor 5138)

Study information

Scientific Title
taRgeted intermittEnt gluCose mOnitoring for the management of GestatioNal dIabeteS mellitus – a feasibility study

Acronym
RECOGNISE

Study objectives
This study is being conducted to explore the feasibility of delivering a full scale multisite randomised controlled trial of intermittently scanned continuous blood glucose monitors (isCGM) compared with usual care (SMBG; self-monitoring of blood glucose) for women with gestational diabetes mellitus who require metformin or insulin.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 31/08/2022, South Central - Berkshire B Research Ethics Committee (Whitefriars, Level 3, Block B, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8178, +44 (0)207 104 8121; berkshire.rec@hra.nhs.uk), ref: 22/SC/0246

Study design
Interventional feasibility study

Primary study design
Interventional

Study type(s)
Prevention

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

Interventions
Intermittently scanned continuous blood glucose monitoring device (Freestyle Libre2). Administered approximately 1-2 weeks post-diagnosis, following commencement of metformin or insulin. Worn for the remainder of the pregnancy (changed every 14 days).

Control: The control group will self-monitor blood glucose using a paper diary or smartphone application (app) diary (GDm-Health). They will also be given a masked isCGM device (FreeStyle Libre Pro iQ) to wear for 14 days at two time points: baseline and ~34 weeks gestation of pregnancy.

Women will be randomised in a 2:1 ratio to is CGM device or SMBG using a secure, web-based randomisation system. The allocation will not be revealed until sufficient data to identify the participant has been entered to ensure allocation concealment. The randomisation will consist of minimisation by site, gestation at diagnosis (early/late), and insulin required (yes/no), to ensure balance across groups.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Freestyle Libre2, FreeStyle Libre Pro iQ

Primary outcome(s)
Feasibility outcomes measured using data recorded in the study screening log at the end of the study:
1. Absolute number of recruits
2. Recruitment rate
3. Number of women invited to study
4. Number of women meeting eligibility criteria
5. Follow-up rate

Key secondary outcome(s))
Clinical fetal/neonatal outcomes (at birth and 6-8 weeks postnatal where indicated) measured using the participants' clinical record:
1. Birth centile including large and small for gestational age (LGA; SGA); Intergrowth birth centile chart. LGA >90th centile SGA<10th centile at birth
2. Birth weight (g) at birth
3. Fetal macrosomia >4kg (Yes/No) at birth
4. Anthropometry: Head, chest, abdominal circumference (cm); crown-rump length, crown-heel length at birth and weight and head circumference at birth and 6-8 weeks postnatal
5. Miscarriage before 23+6 gestation (Yes/No) recorded when the event arises
6. Stillbirth after 24+0 gestation (Yes/No) recorded when the event arises
7. Neonatal death <28 days of life (Yes/No) recorded when the event arises
8. Preterm birth <37 weeks' gestation at birth (Yes/No) at birth
9. Gestation at birth (weeks) at birth
10. NICU admission (Yes/No) and length of stay in days at birth
11. Umbilical cord pH at birth
12. Apgar score at 0, 5, and 10 minutes at birth
13. Injury: clavicle, humeral, skull fracture (Yes/No) at birth
14. Hypoglycaemia requiring NICU treatment (Yes/No) at birth
15. Treatment for Respiratory distress syndrome (Yes/No) at birth
16. Treatment for hyperbilirubinaemia (Yes/No) at birth

Clinical maternal outcomes measured using data recorded in Clinical records:
17. Weight (kg) at booking and 34-36 weeks
18. Height (cm) at booking and 34-36 weeks
19. Diabetes medications prescribed (type, quantity) at each appointment
20. Hypoglycaemic episodes (if on insulin) (number/ frequency) at each appointment

21. Other adverse events (e.g. skin irritation) at each appointment
22. Glycaemic control:
22.1. HbA1c baseline at 34-36 weeks and 6-13 weeks postnatal for both groups
22.2. SMBG daily diaries – fasting and post-meal glucose. Each antenatal appointment (SMBG group only)
22.3. Continuous glucose data - % time in target range (3.5-7.8mmol/l), area under curve, % time in hypo- and hyperglycaemia, standard deviation and amplitude of glycaemic excursions at baseline and 34-36 weeks for both groups
23. Gestational hypertension/pre-eclampsia per NICE diagnostic criteria(yes/no) at birth
24. Induction of labour (Yes/No) at birth
25. Caesarean birth (pre-labour or intrapartum)/instrumental birth/ vaginal birth (Yes/No) at birth
26. Obstetric and sphincter injury (OASI) (Yes/No) at birth
27. Shoulder dystocia (Yes/No) at birth
28. Postpartum haemorrhage (Yes/No) at birth
29. Maternal hospital stay (days) at birth

Psychosocial, behavioural and health economic (patient-reported) outcomes:
30. Behavioural experiences of blood glucose monitoring measured using a Glucose monitoring experiences questionnaire at baseline and ~34 weeks gestation
31. Physical activity levels amongst pregnant women measured using Pregnancy Physical Activity Questionnaire (PPAQ) at baseline and ~34 weeks gestation
32. Dietary habits of importance in the prevention and management of diabetes measured using the UK Diabetes and Diet Questionnaire (UKDDQ) at baseline and ~34 weeks gestation
33. Medication non-adherence measured using the DOSE measure at baseline and ~34 weeks gestation
34. Anxiety and Depression measured using the Hospital Anxiety and Depression Scale at baseline and ~34 weeks gestation
35. Quality of life measured using the 12-Item Short Form Survey (SF-12), SF-6D and European Quality of Life 5 Dimensions 5 Level Version (EQ-5D-5L) tools at baseline and ~34 weeks gestation
36. Patient-reported resource use measured using the Mother Resource Questionnaire, modified from the Mother & Baby Resource Questionnaire (Warwick University) at baseline and visit 2

Completion date
31/07/2024

Eligibility

Key inclusion criteria
1. Aged 16 - 55 years old
2. GDM diagnosed at any gestation >12 weeks per NICE guidelines: oral glucose tolerance test demonstrating a fasting plasma glucose level of 5.6 mmol/litre or above or a 2-hour plasma glucose level of 7.8 mmol/litre or above
3. Up to 32+0 weeks of gestation
4. Diagnosed within the last 14 days
5. Primiparous or multiparous
6. Singleton pregnancy
7. Not met NICE glucose targets with lifestyle modification of fasting glucose below 5.3mmol

/litre, 1 hour after meals below 7.8mmol/l OR 2 hours after meals below 6.4mmol/litre
8. Commenced insulin and/or at least 500mg/day of metformin
9. Able to give informed consent to participate

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 years

Upper age limit
55 years

Sex
Female

Total final enrolment
60

Key exclusion criteria
1. Aged <16 or > 55 years old
2. Pre-existing overt diabetes (OGTT- fasting ≥7 mmol/L or 2 hour ≥11.1 mmol/Lor HbA1C >48)
3. >32+0 weeks gestation
4. Diagnosis of GDM >14 days
5. Chronic kidney disease
6. Psychiatric inpatient treatment
7. History of bariatric surgery or other surgeries that induce malabsorption
8. Long-term use(>2 weeks) of systemic steroids within 2 weeks prior to enrolment
9. Multiple pregnancies
10. Met NICE glucose targets with lifestyle modification
11. Not prescribed insulin or at least 500mg/day of metformin
12. Unable to give informed consent to participate

Date of first enrolment
15/11/2022

Date of final enrolment
14/10/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
North Bristol NHS Trust
Southmead Hospital
Southmead Road
Westbury-on-trym
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BS10 5NB

Study participating centre
Somerset NHS Foundation Trust
Trust Management
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Sponsor information

Organisation
North Bristol NHS Trust

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?
Protocol article		11/07/2023	12/07/2023	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes