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Monitoring blood sugar levels in pregnancy: comparing continuous glucose monitoring with finger-prick testing for gestational diabetes

Submission date
02/11/2026

Recruitment status
Not yet recruiting

Registration date
09/11/2026

Overall study status
Ongoing

Last Edited
09/11/2026

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Gestational diabetes mellitus (GDM) is a condition where blood sugar (glucose) levels become too high during pregnancy. Around 1 in 5 pregnant women in the UK develop GDM and this number is increasing each year. GDM is more common in women from minority ethnic backgrounds and those living on lower incomes. It can cause serious problems for mothers and babies, including early birth, babies growing too large or too small, admission to neonatal intensive care, and stillbirth or newborn death. Detecting and managing blood sugar levels reduces these risks and can lower costs to the NHS.

Currently, women with GDM monitor their blood sugar using fingerprick tests, also called Self Monitoring of Blood Glucose (SMBG), several times a day. This can be painful and inconvenient and only provides limited information, leading to missed chances to reduce complications from GDM. Continuous Glucose Monitoring (CGM) could be a solution. CGM uses a small sensor worn on the arm to measure blood sugar continuously and send readings to a smartphone or reader. It is painless and provides blood sugar level information 24 hours a day that could help healthcare staff and women to lower blood sugar levels and reduce pregnancy complications.

The RECOGNISED study will recruit pregnant women with GDM from 25 UK maternity centres. Participants will be assigned to one of two groups by randomisation, ensuring both groups are similar. One group will monitor their blood glucose using SMBG (usual care) and the other group will use CGM. RECOGNISED will assess whether monitoring blood glucose using CGM improves outcomes for mothers and babies, reduces NHS costs, and is acceptable to women and healthcare teams, when compared with the current standard of care (SMBG).

Who can participate?
Pregnant women diagnosed with GDM with no other forms of diabetes, and who are being cared for at any hospital participating in the RECOGNISED trial.

What does the study involve?
Patients who agree to take part will be randomly assigned to monitor their blood glucose using

SMBG or CGM until delivery. Participants will be asked to complete questionnaires when they are enrolled, at 34 weeks gestation and at 13 weeks postnatal. Usual care (SMBG) participants will additionally wear a blinded CGM sensor at enrolment and at 34 weeks gestation for two weeks. Some participants will have an additional blood test at 34 weeks gestation to measure HbA1c if that was not previously done as part of their usual care. The research team will also collect routine medical data for the participant (mother) and their baby from randomisation to 13 weeks postnatal. Participants may also take part in an interview to discuss their experiences of the study if they wish to.

What are the possible benefits and risks of participating?
Participants are unlikely to receive any direct benefit from taking part. However, the information collected may help researchers and healthcare professionals better understand different methods of monitoring blood glucose in women with gestational diabetes, which could improve care for future patients.
Participants may experience minor discomfort from using the sensors (e.g. bruising or skin irritation). There is a possibility of sensor malfunction or inaccurate readings, which may require temporary use of finger-prick blood glucose testing instead. Some questionnaires include questions about wellbeing and mental health, which some participants may find upsetting or distressing.

Where is the study run from?
The Bristol Trials Centre, a UK Clinical Research Collaboration registered Clinical Trials Unit, which is part of the University of Bristol's Medical School, UK.

When is the study starting and how long is it expected to run for?
January 2027 to April 2029. Recruitment to the study is expected to start in January 2027 and will continue for 22 months. Following this, there will be 6 months of follow-up, so the study results will not be expected until the end of 2029.

Who is funding the study?
The National Institute of Health and Social Care Research (NIHR) – Health Technology Assessment Programme (NIHR-HTA), UK.

Who is the main contact?
The central trial team, recognised-study@bristol.ac.uk

Contact information

Type(s)
Public

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Type(s)
Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
358288

Central Portfolio Management System (CPMS)
68501

National Institute for Health and Care Research (NIHR)
170211

Study information

Scientific Title
RandomisEd controlled trial of COntinuous Glucose moNItoring in the management of geStational Diabetes mellitus - a multi-centre randomised controlled trial

Acronym
RECOGNISED

Study objectives
Primary objective
Determine the difference between groups for adverse neonatal outcomes at birth (primary outcome; composite outcome of perinatal death, Neonatal Intensive Care Unit (NICU) admission and Large for Gestational Age (LGA) at 28 days post-natal)

Secondary objectives
1. Determine the difference between groups for other maternal and neonatal clinical, and maternal diabetes behaviour/health-related quality of life outcomes
2. Evaluate the cost-effectiveness of CGM compared with self monitoring of blood glucose (SMBG) testing

3. Assess the acceptability of, and obstacles and facilitators to, CGM use via diabetes treatment satisfaction, maternal quality of life and wellbeing outcomes using qualitative interviews and validated questionnaires to inform future implementation in the wider NHS

Ethics approval required
Ethics approval required

Ethics approval(s)
Submitted 26/10/2026, North West – Preston Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8000; preston.rec@hra.nhs.uk), ref: 26/NW/0326

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Metabolic and endocrine, reproductive health and childbirth

Interventions
The RECOGNISED trial is a multi-centre, open-label, parallel group RCT in patients with GDM with internal pilot, embedded qualitative research and a study within a trial (SWAT). In the RECOGNISED trial, pregnant women with GDM, who have no other forms of diabetes, will be randomised in a 1:1 ratio to monitor their blood glucose using either self monitoring of blood glucose (SMBG; usual care) or CGM until delivery.

The trial will aim to recruit 2116 participants with 1058 participants in each arm from 25 UK sites. An internal pilot will establish whether enough locations can be opened to recruitment and eligible patients can be identified, recruited and will adhere to their allocated treatment over the course of the trial to robustly answer the trial questions. The internal pilot will last for 9 months. If the progression criteria are met, the main trial recruitment will continue and patients from the internal pilot will be included in the final analysis.

Randomisation will take place before 32 weeks of pregnancy. Randomisation will be performed by an authorised member of the local research team using a centralised, computer-generated allocation sequence and secure, web-based randomisation service (https://www.sealedenvelope.com/). Participants will be randomised in a 1:1 ratio to CGM or finger prick SMBG (usual care). Randomisation will be minimised by hospital and stratified by GDM in previous pregnancy/ies (Yes/No).

Participants in the SMBG group will be told to continue monitoring their blood glucose using SMBG. Participants in the CGM group will be shown how to use the CGM system. Participants will complete questionnaires at the baseline visit and the research team will record details about them and their pregnancy. Participants in the SMBG group will additionally have a blinded CGM device fitted which they will wear for 2 weeks.

Participants will be followed up at approximately 34 weeks of pregnancy when they will complete more questionnaires and some participants will have an additional blood test to measure HbA1c if this has not been done as part of usual care. The SMBG group will wear another blinded sensor for two weeks. After the delivery of the baby(ies) and at 28 days postnatal the research team will record details about the delivery and the health of the mother and baby(ies). A final follow up will occur at 13 weeks postnatal, where participants will complete some final questionnaires and the local research team will complete a records review to record clinical and resource use information for the mother and baby(ies).

Patients will also be invited to take part in the embedded qualitative study and can optionally consent to the trial team audio-recording the interviews about their experience. Additionally, a SWAT (Study Within A Trial) will be embedded into the RECOGNISED study. The SWAT will pilot a co-developed AI recruitment video, which can be translated into other languages, at a small number of sites. Participants can optionally consent to interviews to explore the views of participants on the acceptability of the AI video.

Intervention Type
Mixed

Primary outcome(s)
1. A composite primary outcome of: perinatal death (stillbirth/neonatal death ≤28 days of life), NICU admission, and/or large for gestational age baby (LGA, > 90th birth weight centile for gestational age), measured using data collected from medical notes at the delivery of the baby (ies) and at 28 days postnatal for all recruited participants

Key secondary outcome(s)
1. Glucose control and glucose variability measured using data collected from CGM devices from randomisation to delivery at continuous time points

2. Long term glycaemic control measured using an HbA1c blood test at baseline, 34 weeks gestation and 13 weeks postnatal

3. Clinical maternal outcomes (pre-eclampsia, hypertension, weight gain, diabetes treatment, obstetric anal sphincter injury, miscarriage, termination of pregnancy and delivery admission length) measured using data collected from medical notes at baseline, 34 weeks gestation and delivery

4. Clinical neonatal outcomes (components of primary outcome, duration of NICU stay, gestation at delivery, birth mode, neonatal morbidity, birth weight, feeding method, neonatal unit admissions) measured using data collected from medical notes at delivery and 4 weeks postnatal

5. Adverse events for mother and baby measured using data reported/collected from medical notes at from randomisation to 4 weeks postnatal

6. Maternal diabetes behaviour measured using the Summary of Diabetes Self-Care Activities (SDSCA) at baseline, 34 weeks gestation and 13 weeks postnatal

7. Glucose monitoring satisfaction measured using the Glucose Monitoring Experiences (GME-Q) at 34 weeks gestation

8. Depression measured using the Patient Health Questionnaire 9-item depression scale (PHQ-9) at baseline, 34 weeks gestation and 13 weeks postnatal

9. Health-related quality of life measured using the EQ-5D-5L at baseline, 34 weeks gestation and 13 weeks postnatal

10. Maternal and neonatal/infant hospital admissions, outpatient visits and wider NHS resource use measured using an NHS Resource Use Questionnaire and data collected from medical records at from randomisation to 13 weeks postnatal

Completion date
30/04/2029

Eligibility

Key inclusion criteria
Participants may enter the study if ALL of the following apply:
1. Pregnant, confirmed by presence of foetal heartbeat on either an early viability ultrasound scan performed around 7-8 weeks gestation, or on a dating ultrasound scan at ~12 weeks gestation
2. Diagnosed with GDM in pregnancy by an oral glucose tolerance test (OGTT) per local diagnostic criteria (NICE or SIGN criteria) or by serial glucose monitoring
3. Aged 16 years or above
4. Primiparous or multiparous
5. Singleton or multiple pregnancy
6. Up to 31+6 weeks gestation at diagnosis of GDM
7. Able to give informed consent to participate in the trial

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 Years

Upper age limit

60 Years

Sex
Female

Total final enrolment
0

Key exclusion criteria
Participants may not enter the study (i.e. may not be randomised) if ANY of the following apply:
Women with others forms of diabetes that are not GDM, including type 1 diabetes mellitus, type 2 diabetes mellitus or monogenic diabetes

Date of first enrolment
03/01/2027

Date of final enrolment
31/10/2028

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre
St. James's University Hospital
Beckett Street
Leeds
England
LS9 7TF

Study participating centre
Bradford Royal Infirmary
Chesnut House
Duckworth Lane
Bradford
England
BD9 6RJ

Study participating centre

The Calderdale Royal Hospital
Huddersfield Road
Halifax
England
HX3 0PW

Study participating centre
Liverpool Women's Hospital
Crown Street
Liverpool
England
L8 7SS

Study participating centre
Newham University Hospital
Glen Road
London
England
E13 8SL

Study participating centre
Leicester Royal Infirmary
Infirmary Square
Leicester
England
LE1 5WW

Study participating centre
Royal Derby Hospital
Uttoxeter Road
Derby
England
DE22 3NE

Study participating centre
Milton Keynes University Hospital
Milton Keynes Hospital
Standing Way
Eaglestone

Milton Keynes
England
MK6 5LD

Study participating centre
Norfolk and Norwich University Hospital
Colney Lane
Colney
Norwich
England
NR4 7UY

Study participating centre
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
England
BS10 5NB

Study participating centre
Chelsea and Westminster Hospital
Doughty House
369 Fulham Road
London
England
SW10 9NH

Study participating centre
West Middlesex University Hospital
Twickenham Road
Isleworth
England
TW7 6AF

Study participating centre
Royal Berkshire Hospital
London Road
Reading
England
RG1 5AN

Study participating centre
George Eliot Hospital
Lewis House
College Street
Nuneaton
England
CV10 7DJ

Study participating centre
Jessops Wing
Tree Root Walk
Sheffield
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S10 2SF

Study participating centre
Kings College Hospital
Denmark Hill
London
England
SE5 9RS

Study participating centre
Stoke Mandeville Hospital
Mandeville Road
Aylesbury
England
HP21 8AL

Study participating centre
Watford General Hospital
Vicarage Road
Watford
England
WD18 0HB

Study participating centre

Gloucestershire Royal Hospital
Great Western Road
Gloucester
England
GL1 3NN

Study participating centre
Derriford Hospital
Derriford Road
Derriford
Plymouth
England
PL6 8DH

Study participating centre
Singleton Hospital
Sketty Lane
Sketty
Swansea
Wales
SA2 8QA

Sponsor information

Organisation
Bristol NHS Foundation Trust

ROR
https://ror.org/054vvq170

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

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