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Continuous glucose monitoring amongst pregnant women with early-onset type 2 diabetes

Submission date
19/10/2023

Recruitment status
Recruiting

Registration date
23/10/2023

Overall study status
Ongoing

Last Edited
18/11/2026

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Previous studies have shown that Continuous Glucose Monitoring (CGM) improves maternal glucose, reduces neonatal admissions and is clinically and cost-effective in type 1 diabetes (T1D) pregnancy, and as a result CGM is now standard care in T1D pregnancy. However, there are no well-designed adequately powered trials to compare CGM and standard care monitoring of blood glucose in type 2 diabetes (T2D) pregnancy.

The purpose of this study is to examine whether using CGM improves glucose levels in pregnant women with T2D and whether it leads to better outcomes for the baby. We will also look at its impact on maternal wellbeing, diabetes treatment satisfaction, and cost effectiveness.

Who can participate?
We are aiming to recruit 422 pregnant women aged 16 years and above with T2D.

What does the study involve?
Eligible participants will be approached early in pregnancy and if consent is given they will be enrolled. All participants will wear a masked sensor for 4-14 days to collect baseline CGM data. Participants will then be randomly allocated to receive either study CGM or standard of care (finger-prick blood glucose monitoring) for the rest of pregnancy.

Study visits are aligned with routine antenatal visits every 4 weeks. An optional blood sample for metabolic phenotyping will be obtained, usually at the recruitment visit. The participant will be asked to complete questionnaires at the recruitment visit and then again at around 32 weeks' gestation. Blood samples for HbA1c will be taken at baseline, 28-week, 32-week, and 36-week visits. Participants in the control arm will wear a masked sensor for 14 days at 20, 28, 32 and 36 weeks' gestation. Following delivery we will collect information on birth and infant. 20-25 participants will also be interviewed towards the end of pregnancy, or post-partum, to examine, among other things, barriers and facilitators for CGM use in this population.

What are the possible benefits and risks of participating?
None

Where is the study run from?
University of East Anglia (UK)

When is the study starting and how long is it expected to run for?
May 2023 to May 2028

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

Who is the main contact?
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Additional identifiers

Integrated Research Application System (IRAS)
331906

Central Portfolio Management System (CPMS)
58352

National Institute for Health and Care Research (NIHR)
150958

Study information

Scientific Title
PRegnancy Outcomes using continuous glucose monitoring TEChnology in pregnant women with early-onset Type 2 diabetes: A multicentre randomised controlled trial of the clinical and cost-effectiveness of using continuous glucose monitoring (CGM) in pregnant women with early-onset type 2 diabetes

Acronym
PROTECT

Study objectives
In pregnant women with early-onset type 2 diabetes, the use of real-time CGM is more effective than standard clinical care (finger-prick self-monitoring blood glucose testing, continuous glucose monitoring) for improving the percentage of time spent in the pregnancy target glucose range of 3.5-7.8 mmol/L and reducing clinically relevant neonatal morbidity (neonatal care admission) or perinatal death.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 19/09/2023, South Central - Berkshire B Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 2071048276; berkshireb.rec@hra.nhs.uk), ref: 23/SC/0315

Primary study design
Interventional

Study design
Interventional randomized controlled trial

Study type(s)
Other

Health condition(s) or problem(s) studied
Early-onset type 2 diabetes in pregnancy

Interventions
Recruitment visit: When women have expressed their wish to participate, they will be invited for the recruitment visit, when the following activities will be performed by the research team:
• Checking inclusion and exclusion criteria
• Written informed consent
• Baseline socio-demographic data collection
• Relevant medical / obstetric history and present medical (diabetes, comorbidity, medication, and obstetric) information
• Body weight and height, calculation of BMI
• Early pregnancy HbA1c recorded (or performed if not previously done in this pregnancy)
• Blood sample taken for metabolic phenotyping (C-peptide, autoantibodies, genetic risk score)
• Baseline questionnaire pack provided for participants to complete at home (either paper or

electronically via link)
• Masked Freestyle Libre 3 sensor insertion (ideally 2 weeks prior to randomisation)
Women will have a small glucose sensor inserted under the skin by the clinical research team and will be instructed to wear it at home for up to 14 days. They will not be able to see the glucose information from this sensor.

Randomisation visit:
Ideally the sensor will be in place for 14 days, however if necessary to meet timelines, at least 3-4 days of CGM data should be available prior to randomisation (prior to 16 weeks' gestation). At the randomisation visit, the following will be performed:
• Masked CGM sensor upload & review (to confirm adequate baseline data available). Those randomised to the intervention arm will have access to the data from the masked sensor period following randomisation.
• Collection / confirmation of completed baseline questionnaires
• Record average total daily dose (TDD) of insulin during the previous 3 days
• Randomisation via study website
• Participant training
Participants in the CGM group will be shown how to apply the sensor, how to understand and use the CGM apps, how to interpret the data to guide decisions on eating and activity, recommended targets, and metformin / insulin dose adjustment.
Participants in the control arm will receive fingerstick self-monitoring blood glucose or continuous glucose monitoring training per local standard of care, along with advice on recommended targets, managing their diabetes in pregnancy, and metformin/insulin dose adjustment if relevant.
Participants will use their allocated glucose monitoring method throughout pregnancy, until after delivery.

Subsequent Study Visits
Follow up visits will be every 4 weeks at ~16/40, 20/40, 24/40, 28/40, 32/40, 36/40. It is expected that study visits will align with routine NHS antenatal clinic visits however virtual study visits will be offered if appropriate.
At these visits the following data will be recorded on the study database:
• Weight
• Blood pressure
• Glucose monitoring method(s), frequency of glucose testing
• Insulin delivery method(s), dose and type
• Adverse events of special interest

In addition, the following will be performed at key visits:
• Masked CGM for control group participants (14 days data collection) at 20, 28, 32, and 36 weeks’ gestation
• Blood collection for HbA1c at 28, 32, and 36 weeks’ gestation
• Follow-up questionnaires at 32 weeks’ gestation

Delivery visit
The following obstetric and neonatal outcomes will be collected:
• Mode of delivery (vaginal, instrumental, elective/emergency caesarean section)
• Gestational age at delivery and indication for any preterm delivery <37 weeks
• Infant(s) birth weight
• Adverse events (pregnancy loss <24 weeks, stillbirth, neonatal death)

Neonatal follow up
Neonatal assessment is at hospital discharge (or 28 days if admission prolonged). The following data will be collected:
• Neonatal morbidity (treatment for neonatal hypoglycaemia, neonatal jaundice, respiratory distress)
• Neonatal care admission (duration of stay at each level of care)
• Infant feeding at hospital discharge
• Neonatal readmission in first 7 days after birth

Questionnaires
Participants will be asked to complete questionnaires at home, electronically or on paper, at baseline and again at 32 weeks:
• T2D Distress Scale (DDS)
• Glucose Monitoring Satisfaction Survey (GMSS)
• Patient Health Questionnaire 9-item depression scale (PHQ-9)
• Generalized Anxiety Disorder 7-item scale (GAD-7)
• EQ-5D

Optional qualitative interviews
20-25 participants will be purposively selected by socio-demographic factors to take part in the semi-structured interviews, in early pregnancy (after randomisation) and again at around 32-36 weeks' gestation. Interviews will take place remotely or in person.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Continuous glucose monitoring

Primary outcome(s)
1. Percentage time spent with maternal glucose levels within target range as recorded by CGM Time-In-Range (TIR 3.5-7.8mmol/l) from 20 until 38 weeks' gestation or until delivery, if delivery is earlier than 38 weeks' gestation
2. Neonatal unit admission or death (stillbirth/neonatal death) From randomisation to discharge after delivery (or 28 days post delivery if admission prolonged)

Key secondary outcome(s)
1. HbA1c & CGM mean glucose, GMI, frequency & duration of glycaemic excursions [%Time-Above-Range (≥6.7 & ≥7.8mmol/L), %Time-Below-Range (≤3.5 & ≤3.0mmol/l)], glycaemic variability (glucose SD, CV)] From 20 until 38 weeks' gestation or until delivery, if delivery is earlier than 38 weeks' gestation
2. Hypertensive disorders from randomisation to discharge after delivery (or 28 days post delivery if admission prolonged)
3. Gestational weight gain from baseline (early pregnancy) to last visit prior to delivery
4. Diabetes treatment (metformin & insulin use) From 20 until 38 weeks' gestation or until delivery, if delivery is earlier than 38 weeks' gestation
5. Hospital admissions & duration of stay from randomisation to discharge after delivery (or 28 days post delivery if admission prolonged)

6. Severe hypoglycaemia, hyperosmolar hyperglycaemic state, and diabetic ketoacidosis episodes from randomisation to discharge after delivery (or 28 days post delivery if admission prolonged)
7. Gestational age at birth
8. Birth weight for gestational age (SDS) (GROW customised birth weight, LGA birth weight >90th centile or SGA <10th centile) at Birth
9. Mode of delivery at delivery
10. Neonatal unit admission >24hrs (duration of stay, highest level care) at Discharge after delivery
11. Adverse events (pregnancy loss <24 weeks, congenital anomaly (any), stillbirth, neonatal death) at Delivery
12. Birth injury (spinal cord injury, clavicular, skull or bone fracture, shoulder dystocia, nerve palsy, subdural or intracerebral haemorrhage, hypoxic ischaemic encephalopathy) at Birth
13. Neonatal morbidity (treatment for neonatal hypoglycaemia, respiratory distress requiring treatment, neonatal jaundice requiring treatment) at Discharge after delivery
14. Feeding at hospital discharge (exclusive breast-feeding / partial breast-feeding / exclusive formula feeding) at Discharge after delivery
15. Diabetes distress, anxiety & depression and treatment satisfaction using short questionnaires at Baseline & 32 weeks' gestation
16. Qualitative study to explore the acceptability, barriers, and facilitators for CGM use in T2D pregnancy at Baseline & 32-36 weeks' gestation
17. Incremental cost per quality-adjusted life year (QALY) at Randomisation to discharge after delivery

Completion date
31/05/2028

Eligibility

Key inclusion criteria
Current key inclusion criteria as of 12/03/2026:

1. Type 2 diabetes (T2D)
2. 16 years of age or over
3. Confirmed pregnancy
4. HbA1c of > = 43 mmol/mol (6.1%) in pregnancy (prior to randomisation)
5. Willingness to use the study devices throughout the trial
6. Able to provide informed consent
7. 4 days (aiming for ≥96 hours) of baseline CGM data before randomisation at no later than 16+0 weeks' gestation. In cases where 72-96 hours of CGM data is available, inclusion may be approved by the NCTU team

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Previous key inclusion criteria:

1. Type 2 diabetes (T2D)
2. 16 years of age or over
3. Confirmed pregnancy < = 14 weeks' gestation

4. HbA1c of >=43 mmol/mol (6.1%) in pregnancy (<=14 weeks' gestation)
5. Willingness to use the study devices throughout the trial
6. Able to provide informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 Years

Upper age limit
120 Years

Sex
Female

Total final enrolment
0

Key exclusion criteria
Current key exclusion criteria of of 12/03/2026:

1. Non-type 2 diabetes
2. Chronic kidney disease (CKD) grade 4 or 5 (GFR < 30ml/min)

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Previous key exclusion criteria:

1. Non-type 2 diabetes
2. Chronic kidney disease (CKD) grade 4 or 5 (GFR < 30ml/min)
3. Severe visual impairment

Date of first enrolment
01/01/2024

Date of final enrolment
30/04/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Norfolk and Norwich University Hospitals NHS Foundation Trust
Colney Lane
Colney
Norwich
England
NR4 7UY

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

Study participating centre
University College London Hospitals NHS Foundation Trust
250 Euston Road
London
England
NW1 2PG

Study participating centre
Birmingham Women's and Children's NHS Foundation Trust
Steelhouse Lane
Birmingham
England
B4 6NH

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary
Infirmary Square
Leicester
England
LE1 5WW

Study participating centre
West Hertfordshire Teaching Hospitals NHS Trust
Trust Offices
Watford General Hospital
Vicarage Road
Watford
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WD18 0HB

Study participating centre
Imperial College Healthcare NHS Trust
The Bays
St Marys Hospital
South Wharf Road
London
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W2 1BL

Study participating centre
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MK6 5LD

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Study participating centre
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Study participating centre
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E1 2ES

Study participating centre
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L8 7SS

Study participating centre
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Study participating centre
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Study participating centre
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John Radcliffe Hospital
Headley Way
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TW7 6AF

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Study participating centre

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WF8 1PL

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WF1 4DG

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Lister Hospital
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Study participating centre
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AL7 4HQ

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PE21 9QS

Study participating centre
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SE13 6LH

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Sponsor information

Organisation
University of East Anglia

ROR
https://ror.org/026k5mg93

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

Results and Publications

Individual participant data (IPD) sharing plan

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			18/11/2026	Yes	No