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Improving uptake of screening for type 2 diabetes after a diagnosis of gestational diabetes in pregnancy: is a home blood test the answer?

Submission date
18/09/2025

Recruitment status
No longer recruiting

Registration date
24/09/2025

Overall study status
Completed

Last Edited
05/02/2026

Condition category
Nutritional, Metabolic, Endocrine

[_] 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 the name for diabetes that develops in pregnancy. It is recommended that all women with GDM have a follow-up blood test after delivery to check that their blood sugars are normal. This blood test is called an 'HbA1c' and it is normally taken around 13 weeks after their baby is born, to make sure that blood sugars have normalised. This is important as a small number of women will have high blood sugars which may indicate that they have type 2 diabetes or are at high risk of developing this in the near future.
People who have GDM, are ten times more likely to go on to develop type 2 diabetes at some point in their lives. For this reason it is also recommended that people with a history of GDM have their HbA1c level taken once a year.
At the moment women with GDM are invited to attend a clinic to have this blood test done. Although this is the correct test to screen for type 2 diabetes, we know that some women struggle to attend these appointments and therefore do not have their blood level checked. This study is trialling a HbA1c blood test which is taken at home, to see if it improves the number of people who have HbA1c testing after a pregnancy affected by GDM. We also hope to gain an understanding of how people feel about doing an at-home test, rather than visiting a clinic for one, in order to assess whether at home tests might provide an alternative to in-clinic testing for NHS patients in the future.

Who can participate?
Patients aged 16 to 55 years with gestational diabetes having their antenatal care in NHS Lothian

What does the study involve?
Around 13 weeks after delivery the research team will send participants a HbA1c blood testing kit in the post to do at home. This kit will need to be returned via a post box. Participants will be sent one reminder to carry out the blood test at around 15 weeks postpartum. As the home test replaces the in-person test usually taken in clinic should a participant not return the home blood test by 16 weeks postnatal they will be sent an appointment to attend clinic to have it

performed.
The home blood test involves using a very small handheld needle device to prick the finger in order to collect around 5-6 drops of blood in a small bottle. After taking the blood, the kit instructions will be sent by tracked post back to the laboratory who will analyse it.
The home blood test kit is not provided and analysed by the NHS. It is provided by a third party company (Forth, a trading name of Humankind Ventures Ltd, https://www.forthwithlife.co.uk). This company and the labs analysing the samples meet all the necessary standards to process participant samples accurately and securely.
If participants choose to do the home blood test, their result will be sent to them by the research team in the post. They will also be asked to complete an online survey to help the team understand their experiences of the home testing kit. Test results will also be shared with participants' GPs. If out with normal range the result will be shared with the NHS Lothian diabetes team, who will arrange a follow-up appointment.

What are the possible benefits and risks of participating?
Participants may or may not find it more convenient to take their postnatal HbA1c test at home. There are otherwise no direct benefits to taking part in this study, but the results from this study might help to improve the healthcare of patients in the future.

Where is the study run from?
The study is run by the Edinburgh Pregnancy Research Team at the University of Edinburgh. They are currently based within the Royal Infirmary of Edinburgh (UK).

When is the study starting and how long is it expected to run for?
February 2025 to May 2026

Who is funding the study?
Chief Scientist Office (UK)

Who is the main contact?
Prof. Rebecca Reynolds, r.reynolds@ed.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Rebecca Reynolds

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Additional identifiers

Integrated Research Application System (IRAS)
356021

Central Portfolio Management System (CPMS)
69531

Protocol serial number
AC25046

Study information

Scientific Title
MyGDM Scotland: Home HbA1c Testing Pilot

Study objectives
Primary Objectives:
1. To assess patient uptake of home HbA1c testing for type 2 diabetes screening in a 3 – 4-month postpartum population diagnosed with gestational diabetes during pregnancy.

Secondary Objectives:
1. To measure participant satisfaction with home HbA1c testing for type 2 diabetes screening in the postnatal period.
2. To gather participant views regarding postnatal type 2 diabetes screening and possible modifications to follow-up care to optimise uptake.
3. To gather data on trial recruitment rates and factors affecting recruitment to this pilot trial to guide sample size calculations and study design decisions prior to undertaking a larger clinical trial.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 17/06/2025, South Central -Berkshire B Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)2071048029; berkshireb.rec@hra.nhs.uk), ref: 25/SC/0162

Primary study design
Interventional

Study design
Prospective single-arm pilot trial

Study type(s)
Screening

Health condition(s) or problem(s) studied
Screening for type 2 diabetes in patients with a history of gestational diabetes

Interventions
Participants will be sent a HbA1c blood testing kit in the post to do at home rather than attending an in-person clinic appointment. The home blood test involves using a small handheld needle device to collect around 5-6 drops of blood into a small bottle. After taking the blood, participants will send it by tracked post back to the laboratory that will analyse it. The blood test result will be sent to participants by the research team in the post and participants will be asked to complete a short online survey to help the team understand their experience of the home testing kit.

Intervention Type
Other

Primary outcome(s)
The proportion of total trial participants who return their completed home HbA1c test to the lab for analysis and receive their HbA1c test result, therefore completing postnatal type 2 diabetes screening. Assessed between 13-16 weeks following the end of pregnancy for each participant; final outcome calculated upon trial completion.

Key secondary outcome(s)
1. Participant satisfaction with the home HbA1c screening test used for postpartum type 2 diabetes screening, measured using quantitative and qualitative participant survey data at 13-16 weeks following the end of pregnancy for each participant
2. Participant views regarding optimising postnatal screening for type 2 diabetes following a diagnosis of gestational diabetes, collected via participant survey data at 13-16 weeks following the end of pregnancy for each participant
3. The number of patients approached for recruitment into the trial, subsequent trial recruitment rates and reasons participants not recruited, collected via trial pre-screening log at trial completion

Completion date
30/05/2026

Eligibility

Key inclusion criteria
1. Aged 16 to 55 years
2. Under the care of NHS Lothian
3. Diagnosed with Gestational Diabetes this pregnancy as per NHS Lothian guidelines
4. Deemed suitable for postpartum HbA1c testing by the clinical team
5. Able to speak/read/understand a language for which translated documents can be obtained by the research team

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
30

Key exclusion criteria
1. Aged under 16 years old
2. Classified as an Adult with Incapacity (AWI) as determined by the clinical or research team
3. Deemed unsuitable for postpartum HbA1c testing by the clinical team
4. Unable to speak/read/understand a language for which translated documents can be obtained by the research team

Date of first enrolment
14/08/2025

Date of final enrolment
23/10/2025

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Royal Infirmary of Edinburgh at Little France
51 Little France Crescent
Old Dalkeith Road
Edinburgh
Lothian
Scotland
EH16 4SA

Study participating centre
Western General Hospital
Crewe Road South
Edinburgh

Lothian
Scotland
EH4 2XU

Sponsor information

Organisation
University of Edinburgh

ROR
https://ror.org/01nrxwf90

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office, Scottish Government Health and Social Care Directorate

Alternative Name(s)
Chief Scientist Office, Scottish Government Health Directorate CSO, Chief Scientist Office, Scottish Government Health Directorates, Chief Scientist Office of the Scottish Government Health Directorates, Scottish Government Health and Social Care Directorate of the Chief Scientist Office, Scottish Government Health Directorate Chief Scientist Office, The Chief Scientist Office, CSO

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

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			22/09/2025	No	Yes