

# Glycaemic control in labour with diabetes (GILD Trial)

<b>Submission date</b> 10/07/2025	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 16/07/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 22/10/2025	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Diabetes during pregnancy affects about 9 in every 100 women or birthing people. Most of these cases are gestational diabetes (GDM), which develops during pregnancy and usually goes away after birth. During labour or before a planned caesarean, people with GDM are often closely monitored to keep their blood sugar levels in a safe range. However, some find this monitoring uncomfortable or intrusive. New research suggests that very tight control of blood sugar during labour might not be as necessary as once thought. This study will compare two approaches—tight control and a more relaxed approach—to see how they affect the birth experience, the baby's health, and overall outcomes.

### Who can participate?

You may be able to take part if you:

- Have gestational diabetes
- Are aged 16 years or over (or under 16 years if considered able to consent)
- Are expecting one baby (not twins or more)
- Are planning to give birth at 37 weeks or later
- Can give informed consent

### What does the study involve?

If you join the study, you'll be randomly placed into one of two groups during labour:

- One group will have their blood sugar checked every hour, aiming to keep levels between 4–7 mmol/L.
  - The other group will have checks every 2–4 hours, with a wider target range of 4–10 mmol/L.
- If your blood sugar goes outside the target range, you'll be treated with insulin as part of usual care.

Researchers will also ask you about your experience of the monitoring and your birth.

### What are the possible benefits and risks of participating?

Taking part in the study may not directly benefit participants, but the information we collect from this study may help us to understand more about the best way to monitor blood sugars during labour in people with gestational diabetes. This may be of benefit to participants' in a future pregnancy and may help all women/birthing people with GDM in the future.

Whilst recent research suggests tight monitoring of blood sugars may not be as important for preventing problems in the baby as once thought, we do not know which one is better for women/birthing people and their babies. That is why we are doing this study. When women's blood sugars are monitored in labour closely, about 10 in every 100 babies (i.e., 10%) have low blood sugars after birth, which could mean the baby is admitted to the neonatal unit, away from their Mum, for treatment. If a woman/birthing person's blood sugars are monitored labour in a 'more relaxed' approach, we think about 15 in 100 babies (i.e., 15%) might have low blood sugars after birth, but we don't know - it might be slightly less, it might be slightly more. There are no physical risks from completing the questionnaires or optional discussions. It is possible that thinking and talking sensitive topics such as gestational diabetes and birth experience may cause feelings of anxiety.

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

When is the study starting and how long is it expected to run for?  
October 2024 to January 2028

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

Who is the main contact?  
GILD@nottingham.ac.uk

## Contact information

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Public

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**Type(s)**  
Scientific, Principal investigator

**Contact name**  
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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

333765

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

CPMS 58451, NIHR159223

## Study information

### Scientific Title

The clinical and cost effectiveness of tight versus more relaxed glucose control around the time of birth in pregnancies complicated by gestational diabetes (GILD)

### Acronym

GILD

### Study objectives

'More relaxed' blood glucose control is non inferior to 'tight' control around the time of birth for women/birthing people with Gestational Diabetes Mellitus (GDM) for risk of neonatal hypoglycaemia and neonatal unit admission

### Ethics approval required

Ethics approval required

### Ethics approval(s)

approved 16/06/2025, East of England - Cambridge East Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 2071048181; cambridgeeast.rec@hra.nhs.uk), ref: 25/EE/0116

### Study design

Interventional randomized controlled trial

### Primary study design

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Glycaemic control in labour with diabetes

## **Interventions**

### Main study

When the woman/birthing person comes into hospital to birth their baby, the clinical team providing intrapartum care will follow the glucose monitoring strategy as per randomised allocation:

Tight monitoring (comparator) – glucose finger prick testing will be conducted hourly, and the acceptable blood sugar range will be 4–7 mmol/L.

More relaxed monitoring (intervention) – glucose finger prick testing will be conducted every 2–4 hours, and the acceptable blood sugar range will be 4–10 mmol/L.

Glucose testing by finger prick testing will commence from the point of:

- i) admission in either spontaneous established labour, or
- ii) following artificial rupture of membranes or onset of regular contractions following induction of labour, or
- iii) admission for elective caesarean section

Data on the birth, maternal health outcomes and neonatal health outcomes will be collected between admission for birth and hospital discharge. At the time of discharge, women/birthing people will complete questionnaires about their birth experience and quality of life. A follow-up questionnaire will also be completed at 6 weeks after birth and an economic evaluation will be undertaken.

To determine acceptability of more relaxed glucose control, some women/birthing people and healthcare practitioners will be interviewed.

### Qualitative sub-study

Women/birthing people: Approximately 20 women/birthing people will be purposively sampled via a pre-defined sampling matrix. At the point of consent for the main trial, women/birthing people can give optional consent to be contacted about the qualitative sub-study. At around 6 weeks post-birth the women/birthing people will be provided with an information sheet about the qualitative sub-study and if they agree to take part an interview will be arranged for between 6 and 12 weeks post-birth. Verbal consent will be collected and recorded by the researcher before the start of the interview. Interviews will last around 30–45 minutes and will follow an interview theme guide. A £25 shopping voucher will be offered as a token of appreciation upon interview completion.

Healthcare professionals: One-to-one semi-structured interviews will be conducted with approximately 20–30 health professionals (e.g. clinical midwives, neonatologists, obstetricians, diabetes specialists) or until data richness is achieved from participating sites, who have experience of either caring for women/birthing people who have been randomised to the more relaxed blood glucose monitoring strategy or caring for infants born to women/birthing people who were randomised to more relaxed control. Purposive sampling will ensure health professionals of different career stages, ethnicities and locations are included. A remote interview, via telephone or video call, will be convened at a mutually convenient time. Consent will be taken verbally and recorded electronically at the beginning of the interview. Health professionals will be offered the opportunity to enter into a £250 prize draw upon completion of interview.

## Study within a trial (SWAT)

Participating sites will be randomised on a 1:1 allocation to receiving standard recruitment materials or standard recruitment materials plus an inclusivity package. The inclusivity package will include bespoke trial recruitment materials for South Asian women/birthing people, cultural awareness training for site staff provided in line with the site initiation training, and community connectors. Community connectors will be women/birthing people with lived experience of gestational diabetes who will provide ad-hoc informal peer-support to women/birthing people who are considering joining the trial. Sites will be randomised using a minimisation algorithm balancing on baseline South Asian ethnicity at site (ONS/site level data). Randomisation will be by NCTU prior to site initiation.

Sites not randomised to receive the inclusivity package will receive standard trial recruitment materials. To ensure these sites are still supported to recruit underserved groups, including South Asian women/birthing people, standard trial materials will be translated to the top five languages at the participating sites.

## Intervention Type

Other

## Phase

Not Specified

## Primary outcome(s)

Co-Primary outcomes:

1. Neonatal hypoglycaemia, as defined by a blood glucose level of  $<2$  mmol/L at any time and/or a single value of  $<2.5$  mmol/L in a baby with abnormal clinical signs. Tested using a blood gas analyser, between birth and neonatal discharge after birth.
2. Neonatal unit admission (any level; 1-3) at any point between birth and neonatal discharge after birth measured using patient records.

## Key secondary outcome(s)

Measured using patient records (unless noted otherwise):

Secondary outcomes (neonatal):

1. Outcome of birth, defined as live/stillbirth.
2. Symptomatic neonatal hypoglycaemia, measured on a 'symptoms checklist' between birth and neonatal discharge after birth.
3. Treatment for neonatal hypoglycaemia between birth and neonatal discharge after birth.
4. Duration of neonatal unit admission between birth and neonatal discharge after birth.
5. Neonatal hypothermia, defined as any episode  $<36.5^{\circ}\text{C}$  between birth and neonatal discharge after birth.
6. Hypoxic ischaemic encephalopathy (HIE) requiring active therapeutic hypothermia between birth and neonatal discharge after birth.
7. Neonatal death less than or equal to 28 days since birth.
8. Breastfeeding, captured in the CRF between birth and neonatal discharge, and a participant-completed questionnaire at 6 weeks post-birth.

Secondary outcomes (maternal)

9. Maternal hypoglycaemia defined as blood glucose  $< 3.5$  mmol/L, measured using capillary blood glucose values during admission for birth.
10. Maternal admission to critical care, between admission for birth and maternal discharge after

birth.

11. Postnatal depression. Measured using the Edinburgh Postnatal Questionnaire, completed by the participant 6 weeks after birth.

Secondary outcomes (treatment acceptability and adherence)

12. Maternal satisfaction with childbirth experience. Measured by Birth Satisfaction Scale Revised (validated questionnaire) and selected questions from the Childbirth Experience Questionnaire v2 6 weeks after birth.

13. Maternal satisfaction with blood glucose monitoring strategy. Measured using a study-specific questionnaire at maternal discharge after birth.

14. Woman/birthing person able to eat/drink what they want around the time of birth. Measured via participant-completed questionnaire at maternal discharge after birth.

Secondary outcomes (cost effectiveness)

15. Maternal health-related quality of life, measured using the EQ-5D-5L at baseline, maternal hospital discharge and 6 weeks post-birth.

Secondary outcomes (resource use)

16. The main resources to be monitored include: i) The costs associated with glucose monitoring in labour for both more relaxed control and tight control groups; ii) Time and resource use incurred in NHS secondary care due to maternal or neonatal hypoglycaemia, admission of mothers or babies to neonatal care (any level, 1-3) or to treat any other adverse events; iii) Duration of hospital stay for the woman/birthing person and the baby; iv) Maternal or neonatal re-admissions to secondary care or attendances at primary care or unscheduled postnatal outpatient contacts due to complications attributable to GDM. Measured using participant completed questionnaires at maternal hospital discharge after birth and at 6 weeks post-birth, and data collected from medical records.

Secondary outcomes (acceptability)

17. Acceptability of a more relaxed or tight blood glucose monitoring strategy from the perspective of women/birthing people and healthcare professionals. Measured via qualitative semi-structured interviews between 6-12 weeks after birth.

Secondary outcomes (SWAT)

18. The number of South Asian women/birthing people: i) approached for participation in the trial; ii) who give consent to participate; iii) who are randomised. All proportionate to the number of South Asian women/birthing people at each site. Measured from screening logs and trial enrolment.

### **Completion date**

31/01/2028

## **Eligibility**

### **Key inclusion criteria**

1. Women/birthing people with gestational diabetes mellitus
2. Aged 16 years or over (or < 16 years if deemed Gillick competent).
3. Singleton pregnancy
4. Able to provide informed consent
5. Planned birth  $\geq$ 37 weeks gestation

### **Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

14 years

**Sex**

Female

**Key exclusion criteria**

1. Known lethal fetal anomaly
2. At time of consent, known clinical indication to recommend birth < 37 weeks

**Date of first enrolment**

23/09/2025

**Date of final enrolment**

31/12/2026

**Locations****Countries of recruitment**

United Kingdom

England

Wales

**Study participating centre**

**Queens Medical Centre, Nottingham University Hospital**

Derby Road

Nottingham

United Kingdom

NG7 2UH

**Study participating centre**

**West Middlesex University Hospital**

Twickenham Road

Isleworth

United Kingdom

TW7 6AF

**Study participating centre**  
**Calderdale Royal Hospital**  
Godfrey Road  
Salterhebble  
Halifax  
United Kingdom  
HX3 0PW

**Study participating centre**  
**Chesterfield Royal Hospital**  
Chesterfield Road  
Calow  
Chesterfield  
United Kingdom  
S44 5BL

**Study participating centre**  
**Jessops Wing**  
Royal Hallamshire Hospital  
Glossop Road  
Sheffield  
United Kingdom  
S10 2JF

**Study participating centre**  
**Watford General Hospital**  
Vicarage Road  
Watford  
United Kingdom  
WD18 0HB

**Study participating centre**  
**Princess Anne Hospital**  
Coxford Road  
Southampton  
United Kingdom  
SO16 5YA

**Study participating centre**  
**Northwick Park Hospital**  
Watford Road

Harrow  
United Kingdom  
HA1 3UJ

**Study participating centre**  
**Musgrove Park Hospital (taunton)**  
Musgrove Park Hospital  
Taunton  
United Kingdom  
TA1 5DA

**Study participating centre**  
**Royal London Hospital**  
Whitechapel Road  
Whitechapel  
London  
United Kingdom  
E1 1BB

**Study participating centre**  
**King George's Hospital**  
Barley Lane  
Ilford  
United Kingdom  
IG3 8YB

**Study participating centre**  
**Royal Sussex County Hospital**  
Eastern Road  
Brighton  
United Kingdom  
BN2 5BE

**Study participating centre**  
**Princess Royal Hospital**  
Lewes Road  
Haywards Heath  
United Kingdom  
RH16 4EX

**Study participating centre**  
**St Richards Hospital**  
Spitalfield Lane  
Chichester  
United Kingdom  
PO19 6SE

**Study participating centre**  
**Royal Surrey County Hospital**  
Egerton Road  
Guildford  
United Kingdom  
GU2 7XX

**Study participating centre**  
**St Marys Hospital**  
Oxford Road  
Manchester  
United Kingdom  
M13 9WL

**Study participating centre**  
**Bradford Royal Infirmary**  
Duckworth Lane  
Bradford  
United Kingdom  
BD9 6RJ

**Study participating centre**  
**Croydon University Hospital**  
530 London Road  
Thornton Heath  
United Kingdom  
CR7 7YE

**Study participating centre**  
**Burnley General Hospital**  
Casterton Avenue

Burnley  
United Kingdom  
BB10 2PQ

**Study participating centre**  
**St Thomas' Hospital**  
Westminster Bridge Road  
London  
United Kingdom  
SE1 7EH

**Study participating centre**  
**University Hospital Wishaw**  
50 Netherton Street  
Wishaw  
United Kingdom  
ML2 0DP

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**Queens Medical Centre**  
Derby Road  
Nottingham  
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Reading  
United Kingdom  
RG1 5AN

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Lewisham High Street  
London  
United Kingdom  
SE13 6LH

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Woolwich Stadium Road  
Woolwich  
London  
United Kingdom  
SE18 4QH

**Study participating centre**  
**East Surrey Hospital**  
Canada Avenue  
Redhill  
United Kingdom  
RH1 5RH

**Study participating centre**  
**Darlington Memorial Hospital**  
Hollyhurst Road  
Darlington  
United Kingdom  
DL3 6HX

**Study participating centre**  
**University Hospital of North Durham**  
North Road  
Durham  
United Kingdom  
DH1 5TW

**Study participating centre**  
**Midland Metropolitan University Hospital**  
Grove Lane  
Smethwick  
United Kingdom  
B66 2QT

**Study participating centre**  
**Glangwili General Hospital**  
Dolgwili Road

Carmarthen  
United Kingdom  
SA31 2AF

## Sponsor information

### Organisation

University of Nottingham

### ROR

<https://ror.org/01ee9ar58>

## 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

The current data sharing plans for this study are unknown and will be 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?
<a href="#">Participant information sheet</a>	version 1.1	12/06/2025	16/07/2025	No	Yes