ISRCTN13019598 https://doi.org/10.1186/ISRCTN13019598

Glycaemic control in labour with diabetes (GILD Trial)

Submission date
10/07/2025

Recruitment status
Recruiting

Registration date
16/07/2025

Overall study status
Ongoing

Last Edited
16/07/2025

Condition category
Pregnancy and Childbirth

[ ] 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
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

Type(s)
Public

Contact name
Dr Samantha Harrison

ORCID ID
https://orcid.org/0000-0003-1872-953X

Contact details
Nottingham Clinical Trials Unit, Applied Health Research Building, University Park
Nottingham
United Kingdom
NG7 2RD
-
GILD@nottingham.ac.uk

Type(s)
Scientific, Principal Investigator

Contact name
Prof Kate Walker

ORCID ID
https://orcid.org/0000-0001-5794-7324

Contact details
Nottingham Clinical Trials Unit, Applied Health Research Building, University Park
Nottingham
United Kingdom
NG7 2RD
-
GILD@nottingham.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
333765

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
See study outputs table

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 measure
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.

Secondary outcome measures
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 <36.5C 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 < 3.5mmol/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 Revied (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.

Overall study start date
01/10/2024

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 >=37 weeks gestation

Participant type(s)
Patient

Age group
Adult

Lower age limit
14 Years

Sex
Female

Target number of participants
1630

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
01/07/2025

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
England

United Kingdom

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

Study participating centre
Queens Medical Centre
Derby Road
Nottingham
United Kingdom
NG7 2UH

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

Study participating centre
University Hospital Lewisham
Lewisham High Street
London
United Kingdom
SE13 6LH

Study participating centre
Queen Elizabeth Hospital
Woolwich Stadium Road
Woolwich
London
United Kingdom
SE18 4QH

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

Sponsor information

Organisation
University of Nottingham

Sponsor details
University Park
Nottingham
England
United Kingdom
NG7 2RD
+44 115 951 5151
sponsor@nottingham.ac.uk

Sponsor type
University/education

Website
http://www.nottingham.ac.uk/

ROR

https://ror.org/01ee9ar58

Funder(s)

Funder type
Government

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

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date

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?
Participant information sheet	version 1.1	12/06/2025	16/07/2025	No	Yes