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Improving glucose control for patients with diabetes undergoing surgery

Submission date	Recruitment status	[ ] Prospectively registered
22/01/2025	Recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/05/2025	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
12/05/2025	Nutritional, Metabolic, Endocrine	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This feasibility study will allow the research team to establish potential barriers to completing a larger study regarding perioperative diabetes management and continuous glucose monitoring. This study will help establish both patient and staff acceptability of the implementation of continuous blood glucose monitoring in the perioperative period. This method of blood glucose monitoring is currently not routine practice in the NHS for patients with type 2 diabetes mellitus, and there may be barriers not yet identified which would prevent it from becoming routine.

Who can participate?
Patients over or equal to 18 years of age who have a diagnosis of type 2 diabetes mellitus. Patients must be scheduled for elective urology or gynaecological-oncology surgery within 6 weeks of consenting to be in the trial. Patients must have an expected in-patient stay postoperatively of at least 24 hours.

What does the study involve?
Participants will be recruited and established on a Freestyle Libre 2 system (a non-invasive glucose sensor that is replaced every fortnight and provides 96 glucose readings/day). Patients (and/or nursing staff) will monitor their own blood glucose as per their normal protocol using fingerpick capillary blood glucose readings. Blood glucose readings will be compared to determine the accuracy of both methods, as well as recordings of in-patient hospital outcomes. Participants will complete a questionnaire at the end of the study.

What are the possible benefits and risks of participating?
The researchers do not consider the study to have significant risk for participants. The continuous blood glucose monitoring device (Freestyle Libre 2) may irritate the skin locally causing redness, itching or mild discomfort. On fitting the device the specialist diabetic nurse team will monitor this area and if required remove the device. The researchers have minimised the inconvenience and change to daily activities of a potential further hospital visit to complete a consent process by allowing remote consenting during a phone call. The researchers would consider the use of continuous glucose monitoring during the patient's immediate recovery from surgery to allow patients to monitor their own blood glucose readings a benefit. Routine post-operative care may involve nursing/health care staff testing a patient's blood glucose up to

four times a day, and only at these points would patients know their blood glucose readings and be able to act on them. If a patient is able to check their readings more frequently and at their own convenience they would be able to act on them as they see fit at any point in time. Patients will be able to act promptly and have autonomy over their own blood glucose readings and treatment. The researchers hypothesise that this will minimise the delay of urgent treatment if required. They believe that by giving patients control of their blood glucose readings they will feel engaged in their post-surgery recovery and this may improve their surgical outcomes in the longer term. If a patient is too unwell in the post-operative period to monitor their own blood glucose readings via the Libre device, nursing and health care staff would default to routine care i.e. monitoring the patient's blood glucose via finger prick testing.

Where is the study run from?
University of Leeds and Leeds Teaching Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
December 2021 to March 2026

Who is funding the study?
1. Association of Anaesthetists of Great Britain and Ireland
2. British Journal of Anaesthesia

Who is the main contact?
Prof. Simon Howell, s.howell@leeds.ac.uk

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
353154

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Improving glucose control in patients with diabetes following elective surgical intervention: the role and accuracy of novel glycaemic monitoring

Study objectives
Patients with diabetes mellitus are at higher risk of adverse post-operative outcomes, the reasons for which are not entirely transparent. Optimal glycaemic control in the perioperative period may support patients in achieving the best surgical outcomes possible. Continuous glucose monitoring (CGM) via novel devices should allow diabetic specialist teams and patients to closely monitor their glycaemic trends perioperatively and react accordingly to minimise potential detriment in their recovery. The current study is a feasibility/pilot study to inform the design and delivery of a clinical trial of CGM in non-cardiac surgery patients with type 2 diabetes. The study will also confirm that in hospital CGM gives results congruent to finger prick testing used in standard care.

Ethics approval required
Ethics approval required

Ethics approval(s)
Submitted 22/12/2024, University of Leeds (Research & Innovation Centre, Beckett Street, Leeds, LS9 7TF, United Kingdom; +44 (0)1133437587; governance-ethics@leeds.ac.uk), ref: 2025-NCT 62

Study design
Single-centre non-randomized single-arm trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Type 2 diabetes mellitus (T2DM)

Interventions
Participants will use self-monitoring of blood glucose (capillary finger prick glucose testing as per standard care) for 14 days. Participants will also have continuous glucose monitoring using Freestyle Libre 2 with non-masked glucose readings (readable via their own phone or via monitor provided).

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Freestyle Libre 2 continuous blood glucose monitoring patch

Primary outcome measure
1. Trial procedures for recruitment and perioperative implementation of continuous glucose monitoring (CGM), via Freestyle Libre 2, to inform the design and delivery of a larger study
2. Patient acceptability and recruitment rate for the proposed study measured using the Glucose Monitoring Experiences Questionnaire (GME-Q) on day 14 latest
3. Pilot data to inform the design of a larger study

Secondary outcome measures
1. The accuracy of Freestyle Libre 2 glycaemic monitoring when compared with finger-prick testing in postoperative urology and gynaecology-oncology patients with type 2 diabetes measured at multiple points throughout the postoperative period
2. Time per day (00:00 to 23:59) spent in euglycaemia (3.9-10.0 mmol/l) during hospital admission measured using continuous blood glucose monitoring
3. Time per day (00:00 to 23:59) spent in hypoglycaemia (<3.9 mmol/l) during hospital admission measured using continuous blood glucose monitoring
4. Time per day (00:00 to 23:59) spent in hyperglycaemia (>10.0 mmol/l) during hospital

admission measured using continuous blood glucose monitoring
5. Patient satisfaction with continuous blood glucose monitoring measured using the Glucose Monitoring Experiences Questionnaire (GME-Q) on day 14 latest
6. The incidence of postoperative complications in the perioperative period and the incidence of severe hypoglycaemia measured using continuous blood glucose monitoring by day 30
7. The accuracy and feasibility of using Freestyle Libre monitoring intraoperatively to report blood glucose readings measured using continuous blood glucose monitoring intraoperatively

Overall study start date
01/12/2021

Completion date
01/03/2026

Eligibility

Key inclusion criteria
1. Patients aged ≥18 years at the time of signing the Informed Consent Form
2. Type 2 diabetes mellitus defined as a preadmission diagnosis
3. Scheduled for elective urology or gynaecological-oncology surgery within 6 weeks of consent process
4. Expected in-patient stay of at least 24 hours

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
99 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Unable to provide written informed consent
2. Unable to follow study instructions
3. Diet-controlled type 2 diabetes mellitus
4. Currently using a continuous glucose monitor
5. Day case procedure planned
6. Diabetes other than type 2 diabetes mellitus
7. Dementia or cognitive impairment

Date of first enrolment
01/04/2025

Date of final enrolment
01/12/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
United Leeds Teaching Hospitals NHS Trust
Trust Offices
Leeds General Infirmary
Great George Street
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LS1 3EX

Sponsor information

Organisation
Leeds Teaching Hospitals NHS Trust

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Sponsor type
University/education

Website
http://www.leedsth.nhs.uk/home/

ROR
https://ror.org/00v4dac24

Funder(s)

Funder type
Other

Funder Name
Association of Anaesthetists

Alternative Name(s)
Association of Anaesthetists of Great Britain and Ireland, The Association of Anaesthetists, AAGBI

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Funder Name
British Journal of Anaesthesia

Results and Publications

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

Intention to publish date
01/06/2026

Individual participant data (IPD) sharing plan
Participant-level data will not be made available for this study. This data will be stored on a secure NHS server within Leeds Teaching Hospitals NHS Trust.

IPD sharing plan summary
Stored in non-publicly available repository, Not expected to be made available