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Monitoring blood sugar in patients with diabetes before and after cardiac surgery

Submission date	Recruitment status	[X] Prospectively registered
26/08/2021	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/08/2021	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
04/07/2024	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Diabetes is a lifelong condition that causes a person's blood sugar level to become too high. Improving blood sugar control in patients with diabetes undergoing cardiac surgery is challenging. The disruptive nature of surgery can lead to very high and very low blood sugar readings. Poor control of blood sugar can contribute to complications associated with surgery such as infection. This study proposes to use a “wearable” technology continuous glucose monitor to closely track blood sugar levels during the perioperative period. This monitor is a small patch that sits on the skin and records blood sugar readings for 14 days. The aim of the study is to assess the feasibility of using a glucose monitoring sensor to monitor glucose control in cardiac surgery patients.

Who can participate?
Patients aged 18 years and over with diabetes who require medications to control their blood sugar and are having elective cardiac surgery

What does the study involve?
Participants will be asked to wear a glucose sensor patch on the back of their arm for 1 week before surgery, during their hospital stay and 1 week after discharge from hospital. Patients will still be required to carry out finger-prick glucose monitoring as normal and to record the readings in a diary. Management of their diabetes at home and in hospital will be unchanged from their usual care. Research team members will guide participants on how to apply and remove the sensor. A follow-up phone call is made at 30 days after surgery to check on their recovery.

What are the possible benefits and risks of participating?
As there is no change to the usual diabetes management, there is minimal risk to diabetes control. Minor irritation from wearing the sensor is possible and will be monitored by the research team. The sensor can be removed at any time if there is discomfort. There is not expected to be a direct benefit to the patient. The information from the study may help better manage patients with diabetes in the future.

Where is the study run from?
St Vincent's Hospital Melbourne (Australia)

When is the study starting and how long is it expected to run for?
February 2021 to March 2023

Who is funding the study?
St Vincent's Hospital Melbourne (Australia)

Who is the main contact.
Dr Tuong Phan
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
v1.2, 26th August 2021

Study information

Scientific Title
A prospective exploratory study of perioperative continuous glucose monitoring in adult patients with diabetes undergoing cardiac surgery

Acronym
GLUCOSE-CS

Study objectives
This study aims to investigate continuous glucose monitoring (CGM) metrics' association with perioperative dysglycaemia and perioperative complications in patients with insulin-dependent diabetes undergoing elective cardiac surgery. The current pilot study aims to establish feasibility for a larger study in the future.

The primary end points will be feasibility parameters, including the number of eligible patients at each study site, the consent rate, and the rate of patients successfully completing the study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/03/2021, St Vincent's Hospital Melbourne Research Governance Unit (41 Victoria Parade, Fitzroy, Victoria, Australia; +61 (0)3 9231 2394; research.ethics@svhm.org.au), ref: LRR 330/20

Study design
Prospective observational cohort study

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Glycemic control and perioperative outcomes in patients with diabetes after cardiac surgery

Interventions
1. Wearing the glucose monitoring sensor:
1.1. Application of the monitoring sensor occurs approximately 1 week before surgery. This is a brief process (15 minutes) during a pre-admission outpatient attendance. Where possible this will be coordinated with routine pre-admission appointments. Other periods of sensor application will occur during the hospital stay.
1.2. The sensor will be applied by a member of the research team, such as a nurse or doctor involved in the study, or a nurse who manages patients with diabetes.
1.3. The glucose assessments are recorded automatically and continuously (e.g. every 5 minutes)

once the patch is applied and activated. The results of the glucose measurements are usually summarised as a daily or weekly average.
1.4. The total duration of wearing the sensor will be approximately 3 to 5 weeks. This duration varies for reasons such as the time before admission to hospital, hospital length of stay and how long the sensor remains on the skin.

2. Post-surgery follow up:
2.1. At approximately 1-week post-discharge, a research nurse will contact participants and ask them to remove the sensor and return it in a self-addressed envelope.
2.2. At 30 days after surgery, a phone call of approximately 15 minutes is made to monitor for complications, if any, related to surgery. Often this is part of routine post-surgical follow up and this information is then collected from the hospital records. Where this is not done, a research nurse will make the phone call.

3. Blood glucose monitoring diary:
Participants will be asked to monitor their blood glucose in the usual manner using finger-prick testing before admission and after discharge from hospital. A simple diary will be provided and patients are asked to record the date, time and blood glucose reading when they are taken. During hospitalisation, nurses and doctors will manage blood glucose readings as a routine.

Intervention Type
Device

Phase
Phase III/IV

Drug/device/biological/vaccine name(s)
Abbott FreeStyle Libre Pro Flash Glucose Monitoring System®

Primary outcome(s)
Feasibility 1: The number of eligible patients per week is measured by an audit of the screening and enrolment database at the end of the week
Feasibility 2: The number of recruited patients per week is measured by an audit of the screening and enrolment database at the end of the week
Feasibility 3: The proportion of recruited patients successfully completing the study is measured at 30 days after surgery from an audit of the study database

Key secondary outcome(s))
Measured using the glucose monitoring sensor:
1. Time within target glycaemic range during hospitalisation is measured as the number of hours within the blood glucose range of 3.9-10 mmol/l for the time period starting from the end of surgery until discharge from hospital
2. Time above target glycaemic range during hospitalisation is measured as the number of hours above the glucose level >10 mmol/l for the time period starting from the end of surgery until discharge from hospital
3. Time below target glycaemic range during hospitalisation is measured as the number of hours below the glucose level <3.9 mmol/l for the time period starting from the end of surgery until discharge from hospital
4. Time within target glycaemic range during hospitalisation is measured as the number of hours within the blood glucose range of 3.9-10 mmol/l for the time period starting from discharge from hospital until 7 to 14 days after

5. Time below target glycaemic range during hospitalisation is measured as the number of hours within the blood glucose range below 3.9 mmol/l for the time period starting from discharge from hospital until 7 to 14 days after
6. Time above target glycaemic range during hospitalisation is measured as the number of hours within the blood glucose range greater than 10 mmol/l for the time period starting from discharge from hospital until 7 to 14 days after

7. The proportion of patients with one or more major complications including: acute myocardial infarction, stroke, sepsis, reoperation and mortality is measured using the medical records and a follow-up phone call at 30 days after surgery
8. The proportion of patients with one or more infective complications (%) including: sternal wound infection, other surgical wound infection, pneumonia or urinary tract infection is measured using medical records and patient follow-up phone call at 30 days after surgery
9. Hospital length of stay (days) is measured by accessing patient medical records at the end of the hospital admission

Completion date
30/06/2023

Eligibility

Key inclusion criteria
1. Adult patients aged 18 years and over
2. Diabetes
3. Scheduled for elective cardiac surgery

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
30

Key exclusion criteria
1. Pregnancy
2. Age <18 years
3. Emergency surgery
4. Patients with diabetes on diet control or a single oral hypoglycemic agent

Date of first enrolment
01/09/2021

Date of final enrolment
23/03/2023

Locations

Countries of recruitment
Australia

Study participating centre
St Vincent's Hospital Melbourne
41 Victoria Parade
Fitzroy
Australia
3184

Study participating centre
The Alfred Hospital
55 Commercial Road
Prahran
Australia
3181

Study participating centre
St Vincent's Private Hospital
55 Victoria Parade
Fitzroy
Australia
3065

Sponsor information

Organisation
St Vincent's Hospital

ROR
https://ror.org/001kjn539

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
St Vincent's Hospital

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to an undertaking for the ethics approval that “All data will be accessible only to authorised study investigators” and that “Participants would be informed at the recruitment process that their data may be stored for up to 7 years in a non-identifiable manner and may be used to inform future studies”. Additionally, consent for data sharing has not been written into the consent form for this study. The current study investigators do not have the resources to navigate the issues surrounding sharing sensitive data.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes