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Blood sugar monitoring in people with type 2 diabetes and cancer

Submission date	Recruitment status	[X] Prospectively registered
03/05/2024	Recruiting	[_] Protocol
Registration date	Overall study status	[_] Statistical analysis plan
17/07/2024	Ongoing	[_] Results
Last Edited	Condition category	[_] Individual participant data
17/11/2026	Nutritional, Metabolic, Endocrine	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This research is looking at the ways in which chemotherapy affects the glucose levels in patients with type 2 diabetes. It uses two different ways of monitoring blood glucose (blood sugar) to see if they improve the control of blood glucose levels and if this helps patients complete their planned chemotherapy.

Who can participate?
Patients aged 18 years and over who have type 2 diabetes and are going to receive chemotherapy for colorectal, breast or lung cancer.

What does the study involve?
Participants will be assigned to one of two study groups at random by a computer program. The intervention group will be given Freestyle Libre devices to wear for a total of 6 months, and the control group will be asked to monitor their blood sugar exactly as they normally would (with the exception of the first and last 7 days of their involvement in the study when they will be given a “blinded” Freestyle Libre device to wear). Participants in both arms of the study will also be asked to complete some questionnaires which will ask how they are feeling and how easy or difficult they are finding it to manage their diabetes. These questionnaires should take less than an hour to complete in total.
When participants join the study they will be asked some questions about their health and have routine blood tests taken (to check their HbA1c, kidney function and natural fat levels [lipids]). This will be repeated 6 months after they join. If they are in the intervention group they will have an additional blood test at 90 days from the start of their involvement in the study.
Participants will then be seen by the research team at out-patient clinics, or via telephone depending on preference, on days 14, 21, 28, 90 and 180. Any changes in the chemotherapy that were planned and the reasons for these will also be recorded.
The research team will also call participants by telephone on day 365 (month 12) to check how their health has been. At this time they will also be asked to repeat the questionnaires they completed throughout the study.

What are the possible benefits and risks of participating?
The researchers cannot guarantee that the study will help participants personally. However, the

data collected will provide additional information about the benefit of using different blood glucose monitoring systems in patients with diabetes who are undergoing chemotherapy, and so will hopefully benefit future patients with this condition.
Both sensors use a delivery unit that places the flexible tip into the skin. Participants may experience some mild or moderate symptoms associated with the sensor insertion or the adhesive used to keep the sensor in place. These include redness, swelling, rash, itching, bruising, pain and bleeding. Sensors have to be removed before any medical appointments that include strong magnetic or electromagnetic radiation e.g. an X-ray, radiotherapy, MRI or CT scan and a new sensor applied afterwards.

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

When is the study starting and how long is it expected to run for?
December 2022 to January 2028

Who is funding the study?
Abbott Diabetes Care (UK)

Who is the main contact?
Prof. Ramzi Ajjan, r.ajjan@leeds.ac.uk

Contact information

Type(s)
Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
296415

Central Portfolio Management System (CPMS)
56740

Study information

Scientific Title
Continuous glucose monitoring for improving clinical outcome and quality of life in patients with diabetes and cancer

Acronym
COMMITS-CAN V0.1

Study objectives
In individuals with both type 2 diabetes (T2D) and cancer, flash continuous glucose monitoring (FCGM) improves glycaemic control and increases the success of oncological therapies. This in turn reduces adverse events thereby improving treatment completion rates and quality of life in this vulnerable group of individuals.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/12/2023, East Midlands - Nottingham 2 Research Ethics Committee (Health Research Authority, Redman Place, Stratford, E20 1JQ, UK; +44 (0)207 104 8009, +44 (0)207 104 8065, +44 (0)208 104 8051; nottingham2.rec@hra.nhs.uk), ref: 23/EM/0250

Primary study design
Interventional

Study design
Randomized; Both; Design type: Treatment, Device, Management of Care, Active Monitoring, Qualitative

Study type(s)

Treatment

Health condition(s) or problem(s) studied
Type 2 diabetes and cancer

Interventions
Individuals with type 2 diabetes who are planned to receive chemotherapy as part of the treatment for lung, breast or colorectal cancer will be identified by the oncology team and given details about the study. If they are happy to be involved a consent to contact form will be completed and passed to the diabetes research nurses. The diabetes research nurse will meet with the individual during their oncology pre-assessment appointment and consent the individual. Once the consent has been recorded the baseline assessment will be undertaken and the individual will be randomised to either the control or intervention arm for a total of 6 months. The control arm will be fitted with a blinded sensor, this will take place face-to-face with a diabetes research nurse. The intervention arm will be instructed on the fitting and use of an unblinded sensor. The oncology team and usual diabetes care provider will be the first point of contact for all questions and concerns in those in the control arm, whilst those in the intervention arm will be asked to contact the diabetes research nurse for issues with glycaemic control, while their oncology care remains with the medical team. Out of hours (Monday to Sunday 6 pm to 8 am) healthcare contact regarding diabetes will take place as occurs outwith the trial (out of hours GP, A&E, and oncology).

The sensors and monitors which will be used in this study are supplied by Abbott (the manufacturer) under a direct agreement with the company. The control arm will be encouraged to monitor their blood glucose as they would usually. Those in the intervention arm will be asked to use the FreeStyle Libre device but will not be prevented from using finger prick measurements if they wish to continue doing so. The data from the sensors will be uploaded to a central NHS computer system within each NHS Trust, as in standard clinical practice, which can be accessed by the research team. The data will be transferred to the research team in Leeds with all identifiers removed and study ID included.

Participants will be invited to complete questionnaires throughout the course of the study (a maximum of five at any timepoint with a total completion time of 35 minutes). The questionnaires will be provided in a paper format with participants asked to return completed forms to the study team via the stamped addressed envelope which will be provided by the study team. Questionnaires will be returned for the attention of the medical secretary of the PI, based at Leeds Teaching Hospitals NHS Trust.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Freestyle Libre

Primary outcome(s)
Completion of planned chemotherapy treatment is calculated from instances of dose reduction, early termination of planned treatment and pause in planned treatment at days 14, 21, 28, 90 and 180

Key secondary outcome(s)
1. Infection-related outcomes measured using a count of instances of febrile neutropenia, bacteraemia, sepsis, urinary infection, line-related infections, surgical wound infections and sensor-related infections at days 14, 21, 28, 90 and 180
2. Glycaemic outcomes measured using HbA1c at baseline, days 90 and 180, time in range, eHbA1c, hypoglycaemia (h/day), and glycaemic variability (CoV) and hyperglycaemia (h/day) at days 14, 21, 28, 90 and 180
3. Unplanned admissions to hospital measured using a count of emergency admissions to hospital, lasting ≥24 hours, over the 6-month period following study enrolment
4. Death measured using reports of death within 6 months from study enrolment
5. Patient-reported quality of life measured using EORTC Core Quality of Life questionnaire (EORTC QLQ-C30), EQ-5D-5L, Glucose Monitoring Experiences Questionnaire (GME-Q), Diabetes Self-Management Questionnaire (DSMQ) and Brief Illness Perception Questionnaire (B-IPQ) at baseline, days 14, 28, 180 and 365
6. Cost-effectiveness measured using UKCC at baseline, days 28 and 180

Completion date
31/01/2028

Eligibility

Key inclusion criteria
1. Aged >=18 years at the time of cancer diagnosis
2. Biopsy-confirmed cancer of the colon, rectum, breast or lung. High-grade dysplasia is acceptable with unequivocal radiological evidence of invasive cancer
3. Prior diagnosis of type 2 diabetes (T2D) recorded in primary or secondary care (diet-controlled or requiring hypoglycaemic therapies [including insulin])
4. Cancer care being undertaken at, or managed by, the Leeds Teaching Hospitals NHS Trust, Calderdale and Huddersfield NHS Foundation Trust, Hull University Teaching Hospitals NHS Trust or Sheffield Teaching Hospitals NHS Foundation Trust
5. Planned treatment for cancer includes chemotherapy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Diabetes mellitus diagnosed during the course of active cancer treatment
2. Any diabetes other than T2D
3. Already using the FreeStyle Libre device
4. Inability to give informed consent
5. Known sensitivity to medical adhesives likely to result in an adverse reaction to the Libre device
6. Deemed not suitable for inclusion by study investigators
7. Previous treatment with chemotherapy within 6 months
8. Have a pacemaker or any other neurostimulator

Date of first enrolment
01/09/2024

Date of final enrolment
31/01/2028

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St James's University Hospital
Beckett Street
Leeds
England
LS9 7TF

Sponsor information

Organisation
University of Leeds

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Industry

Funder Name
Abbott Laboratories; Grant Codes: ADC-OUS-IIS-20-51

Alternative Name(s)
Abbott, Abbott U.S., Abbott Alkaloidal Company, The Abbott Alkaloidal Company

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

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?
HRA research summary			17/11/2026	No	No