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Characterisation of sensor accuracy performance for Continuous Glucose Monitoring (CGM) systems

Submission date
19/05/2025

Recruitment status
Recruiting

Registration date
28/05/2025

Overall study status
Ongoing

Last Edited
27/05/2025

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aim
The purpose of this study is to characterize the accuracy performance of different CE-marked CGM.

Who can participate?
Anyone aged 18 years or older with type 1or type 2 diabetes.

What does the study involve?
During this study adult subjects with Type 1 or Type 2 diabetes will wear up to three sensors for a period of up to 31 days depending on each sensor's indications.
During the period of sensor wear participants will go about their normal daily activities while wearing the sensors. Participants will be asked to perform at least four Blood Glucose fingerprick tests per day (before meals and bedtime).

What are the possible benefits and risks of participating?
The data collected in this study could contribute to increase the understanding of available devices to monitor glucose for people living with diabetes as well as giving more people the opportunity to experience the use of CGM devices.
There are small risks associated with use of any sensor device that punctures and adheres to the skin, these include erythema, oedema, rash, itching, bruising, pain, bleeding, induration and infection.
The study participants will perform blood glucose tests. Risks are small but could include pain, bruising, local infection and fainting caused by the lancet used to obtain a blood sample.

Where is the study run from?
The study is run by 2 sites in UK, MAC Clinical Research Glasgow and MAC Clinical Research Barnsley.

When is the study starting and how long is it expected to run for?
June 2024 to April 2035.

Who is funding the study?
The study is funded by Abbott Diabetes Care Ltd (UK).

Who is the main contact?
Dr Pamela Reid, pamela.reid@abbott.com

Contact information

Type(s)
Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
355902

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Characterisation of sensor accuracy performance for CGM systems

Study objectives
The study aims to characterise the performance and collect safety data of different Continuous Glucose Monitoring (CGM) systems in people living with diabetes. Results will be characterised in terms of point accuracy of each CGM system with respect to capillary fingerstick blood glucose values.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 16/04/2025, Yorkshire & The Humber - Leeds West Research Ethics Committee (NHSBT Newcastle Blood Donor Centre Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 207 972 25 04; leedswest.rec@hra.nhs.uk), ref: 25/YH/0073

Study design
Post-market single arm prospective study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Diabetes mellitus

Interventions
Each study arm will involve the use of CE-marked Continuous Glucose Monitoring (CGM) systems. Adults with Type 1 or Type 2 diabetes will wear between one and three sensors for a period of up to 31 days depending on each sensor's wear indications. During the period of sensor wear participants will go about their daily activities and will be asked to perform at least four Blood Glucose (BG) fingerprick tests per day. At Visit 2, sensors are removed, and adverse events are documented, if any.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
CE-marked Continuous Glucose Monitoring (CGM) Systems

Primary outcome measure
The proportion of system readings that are within ±20% for glucose levels ≥70 mg/dL and within ±20 mg/dL for glucose levels <70 mg/dL compared to capillary fingerstick blood glucose (BG) values, over the duration of sensor wear

Secondary outcome measures
Safety outcomes (AEs/ DIs) will be recorded, over the duration of sensor wear

Overall study start date
19/06/2024

Completion date
13/04/2035

Eligibility

Key inclusion criteria
1. Aged at least 18 years old.
2. Have type 1 or type 2 diabetes.
3. Is willing to provide a minimum of 4 and no more than 12 capillary fingerprick blood samples for each day of sensor wear.
4. Is able to read and understand English.
5. In the investigator’s opinion, the participant is willing to wear the sensor(s), to follow the instructions provided to him/her by the study site and perform all study tasks as specified by the protocol.
6. Agrees to continue using their current method of glucose monitoring for duration of study.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Up to 450 participants per year will be enrolled.

Key exclusion criteria
1. Has participated in the same study event.
2. Is a member of the study staff.
3. Is pregnant, planning to become pregnant within the study event duration, or becomes pregnant during the study.
4. Has known (or suspected) allergy to medical grade adhesive at enrolment.
5. Has a skin abnormality at the application sites.
6. Is currently participating in another clinical study that could affect their glucose management.
7. Has a known concomitant medical condition which, in the opinion of the investigator, could present a risk to the safety or welfare of the participant or study staff.
8. Has a pacemaker or any other neurostimulators.
9. Is unsuitable for participation due to any other cause as determined by the investigator.

Date of first enrolment
19/05/2025

Date of final enrolment
01/04/2035

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
MAC Clinical Research Glasgow
Fleming Pavilion, Todd Campus, West of Scotland Science Park
Glasgow
United Kingdom
G20 0XA

Study participating centre
MAC Clinical Research Barnsley
Phoenix House
Maple Road
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Sponsor information

Organisation
Abbott Diabetes Care Ltd.

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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Abbott Diabetes Care Ltd

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 datasets generated during and/or analysed during the current study are not expected to be made available due to the fact the individual participant data is already available to participant and HCP on study completion.

IPD sharing plan summary
Not expected to be made available