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Performance review for FreeStyle Libre Glucose Monitoring Systems

Submission date
13/05/2021

Recruitment status
Recruiting

Registration date
28/06/2021

Overall study status
Ongoing

Last Edited
25/06/2021

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol
Background and study aims
Diabetes is a lifelong condition where the amount of sugar in the blood is too high. The aim of this study is to collect glucose data using the FreeStyle Libre Glucose Monitoring System from adults.

Who can participate?
Anyone aged 18 without diabetes or with type 1 or type 2 diabetes

What does the study involve?
Participants will wear up to four sensors for up to 14 days, after which sensors will be removed, and data uploaded. Each study event aims to recruit between 18 and 72 participants. Once a study event is complete another one commences, on a continuing basis. Each participant is in the study for up to 15 days.

What are the possible benefits & risks of participating?
There is no direct benefit to the participant by taking part in this study. The only risks associated with the study are from obtaining capillary blood samples, these are small but could include pain, bruising, local infection and fainting.

Where is the study run from?
Abbott Diabetes Care (UK)

When is the study starting and how long is it expected to run for?
May 2020 to December 2031

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

Who is the main contact?
Dr Pamela Reid

Contact information

Type(s)
Public

Contact name
Dr Pamela Reid

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
292446

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ADC-UK-PMS-20048, IRAS 292446

Study information

Scientific Title
Sensor accuracy performance review for FreeStyle Libre Glucose Monitoring Systems

Study objectives
Accuracy of FreeStyle Libre Glucose Monitoring Systems compared to capillary fingerstick blood glucose values using the consensus error grid.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/04/2021, West Midlands - South Birmingham Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8345, +44 (0)207 104 8107, +44 (0)207 104 8388; southbirmingham.rec@hra.nhs.uk), REC ref: 21/WM/0064

Study design
Prospective single-arm single-centre study

Primary study design

Observational

Secondary study design
Cross sectional 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
Participants will wear up to four FreeStyle Libre Sensors for up to 14 days. There is no follow-up period unless the participant experiences an unanticipated adverse device effect (UADE).

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
FreeStyle Libre Sensors

Primary outcome measure
Accuracy of the FreeStyle Libre Glucose Monitoring Systems compared to capillary fingerstick blood glucose values (FreeStyle Optium blood glucose test strips) using the consensus error grid at the end of the sensor wear period

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/05/2020

Completion date
31/12/2031

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Has type 1 or type 2 diabetes or has not been diagnosed as having diabetes
3. Be willing and able to test their blood glucose levels at least four times a day

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
18-72 participants per study event

Key exclusion criteria
1. Has another form of diabetes e.g. maturity-onset diabetes of the young (MODY)
2. Have a known (or suspected) allergy to medical grade adhesive
3. Have a skin abnormality at the application sites
4. Have a pacemaker or any other neurostimulators
5. Have concomitant medical condition which in the participant's opinion could interfere with the study or present a risk to their safety or welfare, or that of the study team

Date of first enrolment
01/05/2021

Date of final enrolment
16/12/2031

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Abbott Diabetes Care Ltd
Range Road
witney
United Kingdom
OX29 0YL

Sponsor information

Organisation
Abbott (United Kingdom)

Sponsor details
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Sponsor type
Industry

Website
http://www.abbott.co.uk/

ROR
https://ror.org/03wnay029

Funder(s)

Funder type
Industry

Funder Name
Abbott Diabetes Care

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
Possible presentation at a diabetes conference, and/or publication in a peer-reviewed journal. The estimated timeline is 1 year from the trial end date. No additional documents will be available at this stage.

Intention to publish date
31/12/2032

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 lack of consent to share. All data will be held by Abbott Diabetes Care and used as part of a post-market surveillance program.

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			28/06/2023	No	No