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Performance check and safety data collection of FreeStyle Libre Glucose Monitoring Systems

Submission date
13/02/2015

Recruitment status
Recruiting

Registration date
16/03/2015

Overall study status
Ongoing

Last Edited
26/09/2022

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
The FreeStyle Libre Flash Glucose Monitoring System is a new system for measuring glucose levels and is CE marked and marketed within the UK. The aim of this study is to evaluate the accuracy of the system for people with diabetes, especially those who take insulin.

Who can participate?
Adults aged 18 and over who have type 1 or 2 diabetes.

What does the study involve?
Participants wear the three Sensors according to labelling instructions. The data is transferred and stored in the Reader memory by regular scanning of the Sensor by the participants. Each study event aims to recruit between 18 and 36 participants across approximately 12 sites. Once a study event is complete another one commences, on a continuing basis. Each participant is in the study for up to 15 days. Participants wear a FreeStyle Libre Flash Glucose Monitoring System for 14 days while going about their daily activities. Participants perform four BG fingerstick readings per day for each day of Sensor wear using the built-in test strip port in the Reader to allow evaluation of Sensor accuracy. During Visit 1 participants provide demographic data, and their height and weight are recorded. Participants are trained on how to use the FreeStyle Libre Flash Glucose Monitoring System. They are also instructed to scan the Sensor with the Reader immediately after they do a fingerstick test. Participants return to the clinic on day 15 where their Sensors are scanned before removal and the data is uploaded. This is the end of their study participation. The data is subsequently analysed at Abbott Diabetes Care.

What are the possible benefits and risks of participating?
This study gives participants the opportunity to use flash glucose monitoring as a way of managing their diabetes, which may be of benefit. There are risks associated with the use of any device that punctures the skin. FreeStyle Libre Flash Glucose Monitoring System uses a delivery applicator that places the Sensor ½ cm (or 1/5 inch) into the skin. The participant 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. Blood glucose testing on the Reader may require a few drops (less than 1/100 teaspoon) of blood per day. The risks are the same as the participants' current blood

glucose testing. It may hurt when the lancet goes into the skin; this could produce bruising and a small scar, which could last for several weeks plus there is a low risk of infection. There are similar small risks with the collection of a blood sample for the HbA1c blood test, plus possible dizziness. The amount of blood taken for this test (if one is required) will be up to about 1-2 teaspoons.

Where is the study run from?
Six hospitals in the UK: Oxford Centre for Diabetes, Endocrinology and metabolism (OCDEM), Oxford, The Ipswich Hospital, Ipswich, North Manchester General Hospital, Crumpsall, Royal United Hospital, Bath, Royal Cornwall Hospital, Truro and St James Hospital, Leeds.

When is the study starting and how long is it expected to run for?
January 2015 to December 2027 (updated 17/07/2019, previously: 2026)

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

Who is the main contact?
Dr Pamela Reid

Contact information

Type(s)
Public

Contact name
Dr Pamela Reid

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number
161804

ClinicalTrials.gov number

Secondary identifying numbers
ADC-UK-PMS-14020, IRAS Project ID: 161804

Study information

Scientific Title
Performance check and safety data collection of FreeStyle Libre Glucose Monitoring Systems

Study objectives
The aim of this study is to evaluate the accuracy of the Abbott FreeStyle Libre Flash Glucose Monitoring System, designed for testing of blood glucose for people with diabetes, especially those who take insulin.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee West Midlands - South Birmingham, 17/11/2014, ref: 14/WM/1136

Study design
Multi-centre (12 UK sites) prospective open single-arm study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Other

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

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

Interventions
Current interventions as of 26/09/2022:
Participants wear the three Sensors according to labelling instructions. The data is transferred and stored in the Reader memory by regular scanning of the Sensor by the participants. Each study event aims to recruit between 18 and 36 participants across approximately 12 sites. Once a study event is complete another one commences, on a continuing basis. Each participant is in the study for up to 15 days. Participants wear a FreeStyle Libre Flash Glucose Monitoring System for 14 days while going about their daily activities. Participants perform four BG fingerstick readings per day for each day of Sensor wear using the built-in test strip port in the Reader to allow evaluation of Sensor accuracy. During Visit 1 participants provide demographic data, and their height and weight are recorded. Participants are trained on how to use the FreeStyle Libre Flash Glucose Monitoring System. They are also instructed to scan the Sensor with the Reader immediately after they do a fingerstick test. Participants return to the clinic on day 15 where their Sensors are scanned before removal and the data is uploaded. This is the end of their study participation. The data is subsequently analysed at Abbott Diabetes Care.

Previous interventions:
Participants wear the two Sensors according to labelling instructions. The data is transferred and stored in the Reader memory by regular scanning of the Sensor by the participants. Each study event aims to recruit between 18 and 36 participants across approximately six sites. Once a study event is complete another one commences, on a continuing basis. Each participant is in the study for up to 15 days. Participants wear a FreeStyle Libre Flash Glucose Monitoring System for 14 days while going about their daily activities. Participants perform four BG fingerstick readings per day for each day of Sensor wear using the built-in test strip port in the Reader to allow evaluation of Sensor accuracy. During Visit 1 participants provide demographic data, their height and weight is recorded. Participants are trained on how to use the FreeStyle Libre Flash Glucose Monitoring System. They are also instructed to scan the Sensor with the Reader immediately after they do a fingerstick test. Participants return to the clinic on day 15 where their Sensors are scanned before removal and the data is uploaded. This is the end of their study participation. The data is subsequently be analysed at Abbott Diabetes Care.

Intervention Type
Device

Phase
Not Applicable

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

Primary outcome measure
Accuracy performance of the Abbott FreeStyle Libre Flash Glucose Monitoring System compared to capillary fingerstick blood glucose values (FreeStyle Optium blood glucose test strips) using the consensus error grid. For all primary and secondary outcomes, the data is generated during the Sensor wear period (up to 14 days) during which the participant measures their blood glucose (BG) at least 4 times a day with corresponding Sensor scans. The data recorded in the Reader will be uploaded at visit 2 (day 15) and subsequently transferred to Abbott Diabetes Care (ADC) for analysis. The primary outcome will be measured by calculating the proportion of paired Sensor and BG values within each zone of the Consensus Error Grid.

Secondary outcome measures
1. Precision within Sensor lot estimated by calculating the coefficient of variation of Sensor slopes. Slopes will be calculated for each sensor by standard linear regression of Sensor Glucose vs. BG
2. Relationship between HbA1c levels and glycaemic variability, determined from Sensor glucose values
For all primary and secondary outcomes, the data is generated during the Sensor wear period (up to 14 days) during which the participant measures their blood glucose (BG) at least 4 times a day with corresponding Sensor scans. The data recorded in the Reader will be uploaded at visit 2 (day 15) and subsequently transferred to Abbott Diabetes Care (ADC) for analysis

Overall study start date
13/01/2015

Completion date
31/12/2027

Eligibility

Key inclusion criteria
1. Aged 18 or over
2. Have type 1 or type 2 diabetes
3. Be self-testing their blood glucose levels at least twice per day
4. Be able to follow the instructions provided to him/her by the study site and perform all study tasks as specified by the protocol, in the investigator's opinion
5. Be available for all study visits
6. Be willing to provide written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Each study event will aim to recruit between 18 and 36 participants. A minimum of 360 participants will be recruited per year, with the protocol end date in December 2026, there will be up to 3600 participants recruited in this study protocol

Key exclusion criteria
1. Participated in the same study event
2. Be a member of study staff
3. Have a known allergy to medical grade adhesive
4. Be pregnant or planning to become pregnant within the study event duration
5. Have skin abnormality at the application sites
6. Have a pacemaker or any other neuro stimulators
7. Have concomitant medical condition which in the investigator's opinion could interfere with the study or present a risk to the safety or welfare of the participant or study staff

Date of first enrolment
23/01/2014

Date of final enrolment
31/12/2026

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
North Manchester General Hospital
Delaunays Rd
Crumpsall
Manchester
United Kingdom
M8 5RB

Study participating centre
The Ipswich Hospital NHS Trust
United Kingdom
IP4 5PD

Study participating centre
Oxford University Hospitals NHS Trust
United Kingdom
OX3 9DU

Study participating centre
Royal United Hospital Bath
Combe Park
Avon
United Kingdom
BA1 3NG

Study participating centre
Royal Cornwall Hospital
2 Penventinnie Ln
Treliske
Truro
United Kingdom
TR1 3LQ

Study participating centre

Leeds Teaching Hospitals
St James's University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation
Abbott Diabetes Care Ltd

Sponsor details
Range Road
Witney
United Kingdom
OX29 7NT

Sponsor type
Industry

ROR
https://ror.org/03wnay029

Funder(s)

Funder type
Industry

Funder Name
Abbott Diabetes Care Ltd

Results and Publications

Publication and dissemination plan
Following study completion, results are expected to be submitted for publication. The purpose of this study is to monitor the ongoing analytical performance of the FreeStyle Libre Flash Glucose Monitoring System as part of a post-market surveillance program and therefore would be published as such in accordance with the primary/secondary endpoints described.

Intention to publish date
31/12/2028

Individual participant data (IPD) sharing plan

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IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No