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FreeStyle Libre potential in-reader correction study

Submission date
15/09/2017

Recruitment status
No longer recruiting

Registration date
21/09/2017

Overall study status
Completed

Last Edited
21/11/2024

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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 test the performance of the masked FreeStyle Libre Flash Glucose Monitoring System with and without a potential In-Reader correction, a device designed for people with diabetes to monitor their blood sugar.

Who can participate?
Patients aged 18 and over with type 1 or 2 diabetes

What does the study involve?
Participants wear two masked (blinded) sensors for up to 14 days and take at least four fingerstick blood sugar readings per day whilst wearing the sensors. Participants attend up to six visits at the clinical study site, three of the visits consist of up to 8 hours blood sampling at regular intervals.

What are the possible benefits and risks of participating?
There may be no direct benefit to the participant. The only risks of participating in this study are associated with blood sample collection. These are small but could include pain, bruising, local infection and fainting.

Where is the study run from?
BioKinetic Europe (UK)

When is the study starting and how long is it expected to run for?
September 2017 to March 2018

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
Range Road
Witney
United Kingdom
OX29 0YL

Additional identifiers

EudraCT/CTIS number

IRAS number
230816

ClinicalTrials.gov number

Secondary identifying numbers
ADC-UK-PMS-17031

Study information

Scientific Title
Effectiveness of a potential in-reader correction for FreeStyle Libre flash sensor glucose data

Study objectives
Assess the accuracy of the FreeStyle Libre Flash Glucose Monitoring System measured using percentage of readings that are within ±20% of the YSI reference value for glucose levels ≥ 80 mg/dL (4.4 mmol/L) and within ±20 mg/dL (1.1 mmol/L) for YSI glucose levels <80 mg/dL(4.4 mmol/L), with and without a potential In-Reader correction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Health and Social Care Research Ethics Committee A (HSC REC A), 11/09/2017, REC ref: 17/NI /0156

Study design
Prospective single-arm trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Diagnostic

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

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

Interventions
Participants will wear two masked sensors for a period of up to 14 days. They will be requested to obtain at least four fingerstick readings per day whilst wearing the sensors (using the built-in test strip port in one of the study readers). Participants will have three in-clinic visits; each in-clinic visit will consist of eight hours of reference sampling at 15 minute intervals, from an IV port.

Intervention Type
Device

Phase
Not Applicable

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

Primary outcome measure
The point accuracy of the FreeStyle Libre Flash Glucose Monitoring System, measured using percentage of readings that are within ±20% of the YSI reference value for glucose levels ≥ 80 mg/dL (4.4 mmol/L) and within ±20 mg/dL (1.1 mmol/L) for YSI glucose levels <80 mg/dL(4.4 mmol/L), with and without a potential In-Reader correction. Measured on days 1, 2, 5, 7, 11 and 14 of sensor wear.

Secondary outcome measures
No secondary outcome measures

Overall study start date
15/09/2017

Completion date
31/03/2018

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Type 1 or type 2 diabetes requiring insulin therapy for at least 6 months prior to enrolment
3. Participant reports self-testing their blood glucose levels at least twice per day
4. Suitable venous access for study participation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Approximately 27 participants will be recruited

Total final enrolment
27

Key exclusion criteria
1. Have a known allergy to medical grade adhesive
2. Be pregnant or planning to become pregnant within the study duration
3. Have skin abnormality at the application sites
4. Have a pacemaker or any other neurostimulators
5. 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
6. Have anaemia
7. Currently participating in another clinical study
8. Participant is unsuitable for participation due to any other cause as determined by the Investigator

Date of first enrolment
18/09/2017

Date of final enrolment
28/02/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
BioKinetic Europe
United Kingdom
BT2 7BA

Study participating centre
MAC Research Ltd
Nelson Street
Manchester
United Kingdom
M13 9NQ

Sponsor information

Organisation
Abbott Diabetes Care Ltd

Sponsor details
Range Road
Witney
United Kingdom
OX29 0YL

Sponsor type
Industry

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
Current publication and dissemination plan as of 21/11/2024:
There is no longer a plan to publish the results in a journal.

Previous publication and dissemination plan:
Planned publication in a peer-reviewed journal or conference presentation. Publication date January 2019.

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from ADC_Witney_ClinicalAffairs@abbott.com.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No
Basic results	version 24	21/11/2024	21/11/2024	No	No