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Assessing the use of FreeStyle Libre Pro with HbA1c in diabetes management

Submission date
11/10/2019

Recruitment status
No longer recruiting

Registration date
14/10/2019

Overall study status
Completed

Last Edited
21/11/2024

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background & study aims
Diabetes is a lifelong condition where the amount of sugar in the blood is too high. The aim of this pilot study is to collect glucose data using the FreeStyle Libre Pro Flash Glucose Monitoring System from adults with type 2 diabetes on oral glucose-lowering medication, with or without biphasic insulin

Who can participate?
Patients aged 18 and over with type 2 diabetes on oral glucose-lowering medication, or, oral glucose-lowering medication and biphasic insulin

What does the study involve?
Participants will wear two sensors for up to 14 days (glucose data is not visible during this time). Participants will return to the clinic where the sensors will be removed, and data uploaded

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 venous blood samples, these are small but could include pain, bruising, local infection and fainting. Data collected may be used to support future post-market clinical studies in this population

Where is the study run from?
1. Leeds Teaching Hospitals NHS Trust (Leeds)
2. Atherstone Surgery (Atherstone)
3. Westcliffe Medical Centre (Shipley)
4. Ashfields Primary Care Centre (Sandbach)
5. Kiltearn Medical Centre (Nantwich)
6. Eynsham Medical Group (Eynsham)
7. Trowbridge Health Centre (Trowbridge)
8. Beacon Medical Group (Plymouth)
9. Salford Royal NHS Foundation Trust (Salford)

When is the study starting and how long is it expected to run for?
Proposed start date 21/10/2019 to proposed end date 03/12/2019

Who is funding the study?
The study is funded by Abbott Diabetes Care Ltd

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

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ADC-UK-PMS-19044

Study information

Scientific Title
Pilot Study to Assess use of FreeStyle Libre Pro with HbA1c in Determining Diabetes Management

Study objectives
This pilot study is being conducted to determine whether understanding of diabetes status and management is better with use of HbA1c with FreeStyle Libre Pro than with HbA1c alone

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 07/10/2019, NRES Committee: East Midlands – Nottingham 2 Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS; +44 (0)207 104 8035; NRESCommittee.eastmidlands-nottingham2@nhs.net), ref: 19/EM/0304, IRAS Project ID: 271103

Study design
Prospective open-label multi-centre single-arm pilot study in both hospital and GP practice settings

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
GP practice

Study type(s)
Other

Participant information sheet
No participant information sheet available

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

Interventions
Participants will wear two FreeStyle Libre Pro Flash Glucose Monitoring Sensors for up to 14 days. There is no follow-up period unless the participant experiences an unanticipated adverse device effect (UADE).

Healthcare professionals will complete questionnaires using the HbA1c results alone and also using HbA1c results and the reports generated from the FreeStyle Libre Pro system.

Two sensors are to be applied to allow data collection to continue in case one sensor becomes detached during the study.

Intervention Type
Device

Phase
Not Applicable

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

Primary outcome measure

Responses to HCP questionnaire using HbA1c results alone
Responses to a second questionnaire using HbA1c results and the reports generated from the FreeStyle Libre Pro system

Secondary outcome measures
Glycaemic measures, measured using sensor glucose data collected by the FreeStyle Libre Pro Flash Glucose Monitoring System during the two-week study duration.
1. Time in hypoglycaemia (<3.9 mmol/L)
2. Time in hyperglycaemia (>10.0 mmol/L)
3. Time in range (3.9-10.0 mmol/L)
4. Mean glucose, SD glucose and CV glucose

Overall study start date
01/08/2019

Completion date
23/12/2019

Eligibility

Key inclusion criteria
1. Age at least 18 years
2. Type 2 diabetes, on oral glucose-lowering medication, or, oral glucose-lowering medication and biphasic insulin

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
45

Total final enrolment
44

Key exclusion criteria
1. Currently prescribed basal insulin
2. Currently prescribed bolus insulin
3. Currently prescribed glucagon-like peptide 1 (GLP-1) without being prescribed biphasic insulin
4. Concomitant disease or condition that may compromise patient safety including and not limited to; cystic fibrosis, severe mental illness, a diagnosed or suspected eating disorder or any

uncontrolled long term medical condition
5. Has a pacemaker or any other neurostimulators
6. Currently receiving dialysis treatment or planning to receive dialysis during the study
7. Women who are pregnant, plan to become pregnant or become pregnant during the study
8. Participating in another study of a glucose monitoring device or drug that could affect glucose measurements or management
9. Known (or suspected) allergy to medical grade adhesives
10. In the investigator's opinion the participant is unsuitable to participate due to any other cause/reason

Date of first enrolment
21/10/2019

Date of final enrolment
09/12/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leeds Teaching Hospitals NHS Trust
United Kingdom
LS9 7TF

Study participating centre
The Atherstone Surgery
United Kingdom
CV9 1EU

Study participating centre
Westcliffe Medical Centre
United Kingdom
BD18 3EE

Study participating centre
Ashfields Primary Care Centre
United Kingdom
CW11 1EQ

Study participating centre
The Kiltearn Medical Centre
United Kingdom
CW5 5NX

Study participating centre
Eynsham Medical Group
United Kingdom
OX29 4QB

Study participating centre
Trowbridge Health Centre
United Kingdom
BA14 8QA

Study participating centre
Beacon Medical Group
United Kingdom
PL7 1AD

Study participating centre
Salford Royal NHS Foundation Trust
United Kingdom
M6 8HD

Sponsor information

Organisation
Abbott Diabetes Care Ltd

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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
Possible presentation at a diabetes conference, and/or publication in a peer-reviewed journal. Estimated timeline is one year from trial end date.

Intention to publish date
23/12/2020

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

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			21/11/2024	No	No