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Using the FreeStyle Libre system to monitor blood glucose in insulin-treated patients undergoing dialysis

Submission date
16/11/2018

Recruitment status
No longer recruiting

Registration date
10/12/2018

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 performance data on the masked FreeStyle Libre Flash Glucose Monitoring System with adults with type 1 or 2 diabetes on haemodialysis. FreeStyle Libre Flash Glucose Monitoring System is 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 on haemodialysis

What does the study involve?
Participants will wear a masked Sensor for up to 14 days. Participants will be requested to obtain four fingerprick BG readings per day whilst wearing the Sensor (using the built-in test strip port in the Reader). Participants will be asked to scan the Sensor with the Reader at the same time as each fingerprick BG test, and at regular intervals.
Participants will return to the clinic for Visit 2 where the Sensor 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 capillary blood sample collection, these are small but could include pain, bruising, local infection and fainting. Data collected may be used to support future pivotal trial designs in this population.

Where is the study run from
Churchill Hospital, Oxford & Queen Elizabeth Hospital, Birmingham (UK)

When is the study starting and how long is it expected to run for?
November 2018 to March 2019

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

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

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
251963

ClinicalTrials.gov number

Secondary identifying numbers
ADC-UK-PMS-18038

Study information

Scientific Title
FreeStyle Libre flash glucose monitoring system use in insulin-treated patients undergoing dialysis: a pilot study

Acronym
FLUIDS

Study objectives
Determining whether the performance of the FreeStyle Libre system is different when used by people with diabetes undergoing haemodialysis vs data previously collected on the non-dialysis diabetes population.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee: Yorkshire & The Humber - Bradford Leeds Research Ethics Committee, 08/10/2018, 18/YH/0398

Study design
Interventional prospective multi-centre single-arm pilot study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Diabetes mellitus (type 1 or type 2)

Interventions
Participants will wear a Masked FreeStyle Libre Glucose Monitoring Sensor for 14 days and perform four fingerprick readings per day for each day of sensor wear using the built-in test strip port. There is no follow-up period unless the participant experiences an adverse device effect.

Intervention Type
Device

Phase
Not Applicable

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

Primary outcome measure
1. The accuracy of the system will be measured for the duration the subject is wearing the device (up to 14 days). Each blood glucose result recorded on the reader will be paired with the nearest Sensor glucose result.
2. The safety of the device in the diabetic population sub-group will be measured using the number and percentage of participants experiencing adverse events during the study from the point of consent until the end of the study.

Secondary outcome measures
-

Overall study start date
01/09/2018

Completion date
05/03/2019

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Type 1 or type 2 diabetes
3. Requiring insulin therapy
4. Willing and able to test their blood glucose levels via fingerprick at least four times a day using the FreeStyle Libre System
5. In the investigator's opinion, technically capable of using the study device
6. On stable haemodialysis (i.e. treatment using dialysis has been in progress for a minimum of 90 days)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
25

Total final enrolment
26

Key exclusion criteria
1. Concomitant disease or condition that may compromise patient safety including and not limited to cystic fibrosis, severe mental illness, known or suspected eating disorder or any uncontrolled long term medical condition
2. Currently prescribed oral steroid therapy for any acute or chronic condition
3. Female participant known to be pregnant
4. Have a pacemaker or any other neurostimulators
5. Known (or suspected) allergy to medical grade adhesives
6. In the investigator's opinion, is unsuitable to participate due to any other reason

Date of first enrolment
13/12/2018

Date of final enrolment

30/03/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oxford University Hospital
Oxford
United Kingdom
OX3 9DU

Study participating centre
Queen Elizabeth Hospital
Birmingham
United Kingdom
B15 2WB

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:
Possible presentation at a diabetes conference, and/or 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 will be available upon request from Pamela Reid (Pamela.reid@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			28/06/2023	No	No
Basic results		21/11/2024	21/11/2024	No	No