

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	☒ Prospectively registered ☐ Protocol
Registration date 10/12/2018	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 21/11/2024	Condition category Nutritional, Metabolic, Endocrine	☐ 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

Integrated Research Application System (IRAS)
251963

Protocol serial number
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

Primary study design

Interventional

Study design

Interventional prospective multi-centre single-arm pilot study

Study type(s)

Other

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(s)

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.

Key secondary outcome(s)

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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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

United Kingdom

England

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

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

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?
Basic results		21/11/2024	21/11/2024	No	No
HRA research summary			28/06/2023	No	No