

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

<b>Submission date</b> 11/10/2019	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 14/10/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/11/2024	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> 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. Kiltarn 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

**Contact details**  
Abbott Diabetes Care  
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## Additional identifiers

**Protocol serial number**  
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

### **Study type(s)**

Other

### **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(s)**

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

### **Key secondary outcome(s)**

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

### **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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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**

United Kingdom

England

**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

**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 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?
<a href="#">Basic results</a>			21/11/2024	No	No
<a href="#">HRA research summary</a>			26/07/2023	No	No