

# Retrospective chart review of FreeStyle Libre in adults with type 2 diabetes

<b>Submission date</b> 09/09/2022	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results <input type="checkbox"/> Individual participant data
<b>Registration date</b> 03/10/2022	<b>Overall study status</b> Completed	
<b>Last Edited</b> 24/06/2025	<b>Condition category</b> Nutritional, Metabolic, Endocrine	

## 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 study is to review the effectiveness of the FreeStyle Libre Glucose Monitoring System in adults with type 2 diabetes using insulin.

### Who can participate?

Anyone aged 18 years old and over with type 2 diabetes

### What does the study involve?

For each medical record, HbA1c levels will be collected after 3 to 6 months of use of the FreeStyle Libre sensor and will be compared with their HbA1c levels before starting FreeStyle Libre.

### What are the possible benefits & risks of participating?

There are no direct benefits or risks to patients whose medical records are included.

### Where is the study run from?

Abbott Diabetes Care (UK)

### When is the study starting and how long is it expected to run for?

February 2022 to January 2024

### Who is funding the study?

Abbott Diabetes Care (UK)

### Who is the main contact?

Dr Pamela Reid (UK)  
pamela.reid@abbott.com

## Contact information

Type(s)

Public

**Contact name**

Dr Pamela Reid

**Contact details**

Range Road

Witney

Witney

United Kingdom

OX29 0YL

+44 (0)1993 863024

pamela.reid@abbott.com

## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number**

312330

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

ADC-UK-PMS-22054, IRAS 312330, CPMS 52369

## Study information

**Scientific Title**

A retrospective, non-interventional, chart review study of the effectiveness of FreeStyle Libre in adults with type 2 diabetes

**Acronym**

REFER-UK

**Study objectives**

Effectiveness of FreeStyle Libre flash glucose monitoring system on glycaemic control versus standard of care measured by HbA1c, using patient records

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 02/08/2022, this is a retrospective observational study reviewing medical charts, which does not require ethics approval under the UK's law, ref: 22/NRS/0022

**Study design**

Retrospective non-interventional chart review study

**Primary study design**

Observational

**Secondary study design**

Case series

**Study setting(s)**

Hospital

**Study type(s)**

Prevention

**Participant information sheet**

No participant information sheet available

**Health condition(s) or problem(s) studied**

Diabetes mellitus (diabetes)

**Interventions**

Patient HbA1c levels that were collected 3 to 6 months after the start of FreeStyle Libre are compared to HbA1c levels collected prior to starting Libre.

**Intervention Type**

Device

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

FreeStyle Libre sensor

**Primary outcome measure**

Hemoglobin A1c (HbA1c) level measured using the FreeStyle Libre sensor and recorded in medical charts at baseline and 3 to 6 months after initiation

**Secondary outcome measures**

There are no secondary outcome measures

**Overall study start date**

01/02/2022

**Completion date**

31/01/2024

**Eligibility****Key inclusion criteria**

1. Age 18 years or over
2. Has type 2 diabetes using basal-bolus insulin regimen for at least 1 year

3. Has used FreeStyle Libre/Libre 2 regularly for at least 3 months
4. HbA1c recorded in medical notes between 8.0% and 12.0% (64 to 108 mmol/mol) in the 3 months prior to starting FreeStyle Libre/Libre 2
5. HbA1c recorded in medical notes 3 to 6 months after starting FreeStyle Libre/Libre 2

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

At least 78 medical records that satisfy the inclusion/exclusion criteria

**Total final enrolment**

87

**Key exclusion criteria**

1. Female participant who was pregnant during the data collection period
2. Received dialysis treatment during the data collection period
3. Participated in another device or drug study that could have affected glucose measurements or management during the data collection period

**Date of first enrolment**

04/10/2022

**Date of final enrolment**

11/09/2023

**Locations****Countries of recruitment**

England

Northern Ireland

Scotland

United Kingdom

Wales

**Study participating centre**

**St John's Hospital**

Livingston  
United Kingdom  
EH54 6PP

**Study participating centre**

**Royal Infirmary of Edinburgh**

Edinburgh  
United Kingdom  
EH16 4SA

**Study participating centre**

**Western General Hospital**

Edinburgh  
United Kingdom  
EH4 2XU

**Study participating centre**

**University Hospital Wishaw**

Wishaw  
United Kingdom  
ML2 0DP

**Study participating centre**

**Neath Port Talbot Hospital**

Port Talbot  
United Kingdom  
SA12 7BX

**Study participating centre**

**Morrison Hospital**

Swansea  
United Kingdom  
SA6 6NL

**Study participating centre**

**Singleton Hospital**

Swansea  
United Kingdom  
SA2 8QA

**Study participating centre****Antrim Area Hospital**

Antrim  
United Kingdom  
BT41 2RL

**Study participating centre****Northampton General Hospital**

Northampton  
United Kingdom  
NN1 5BD

**Study participating centre****Southern Health**

Southampton  
United Kingdom  
SO40 2RZ

**Study participating centre****University Hospitals Coventry and Warwickshire NHS Trust**

Coventry  
United Kingdom  
CV2 2DV

## **Sponsor information**

**Organisation**

Abbott (United Kingdom) Diabetes Care Ltd

**Sponsor details**

Range Road  
Witney  
England  
United Kingdom

OX29 0YL  
+44 (0)1993863024  
adc.clinical.affairs.uk@abbott.com

**Sponsor type**  
Industry

**Website**  
<https://www.abbott.co.uk/>

**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**  
1. Planned publication in a high-impact peer-reviewed journal  
2. Presentation at a diabetes conference

Estimated timeline is one year from trial end date

**Intention to publish date**  
30/06/2024

**Individual participant data (IPD) sharing plan**

All study data sourced for this study comes directly from data recorded in medical charts, so can be obtained from original source via appropriate approval, rather than from the sponsor.

**IPD sharing plan summary**

Not expected to be made available

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		04/08/2024	24/06/2025	Yes	No