

Retrospective chart review of FreeStyle Libre in adults with type 2 diabetes using pre-mixed insulin

Submission date 13/01/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 27/01/2025	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 12/02/2025	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and 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 pre-mix insulin.

Who can participate?

Patients aged 18 years or older, with type 2 diabetes

What does the study involve?

For each medical record, HbA1c (a measure of average blood glucose) will be collected after 3 to 6 months of use of the FreeStyle Libre and compared with HbA1c from before starting FreeStyle Libre.

What are the possible benefits and risks of participating?

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

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

June 2024 to June 2025

Who is funding the study?

Abbott Diabetes Care Ltd

Who is the main contact?

Dr Pamela Reid, pamela.reid@abbott.com

Contact information

Type(s)

Public, Scientific

Contact name

Dr Pamela Reid

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Type(s)

Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

350006

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

ADC-UK-PMS-24060, CPMS 65134

Study information

Scientific Title

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

Acronym

REFER-PREMIX

Study objectives

Effectiveness of FreeStyle Libre Glucose Monitoring Systems on glycaemic control versus standard of care measured by HbA1c, using patient records

Ethics approval required

Ethics approval not required

Ethics approval(s)

This is a retrospective observational study reviewing medical charts, which does not require ethics approval. The NHS HRA and UKRI Medical Research Council NHS REC checklist demonstrated that REC review is not required for England and Wales for this study, although the study was submitted and granted HRA and Health and Care Research Wales (HCRW) Approval.

Study design

Retrospective non-interventional chart review study

Primary study design

Observational

Study type(s)

Other

Health condition(s) or problem(s) studied

Type 2 diabetes mellitus (diabetes)

Interventions

For each medical record, HbA1c (a measure of average blood glucose) will be collected after 3 to 6 months of use of the FreeStyle Libre and compared with HbA1c from before starting FreeStyle Libre.

Intervention Type

Other

Primary outcome(s)

Change in HbA1c from baseline to 3 to 6 months after initiation of FreeStyle Libre measured using patient records

Key secondary outcome(s)

There are no secondary outcome measures

Completion date

30/06/2025

Eligibility

Key inclusion criteria

1. Age 18 years or over at the time of starting a FreeStyle Libre system
2. Has type 2 diabetes using pre-mixed insulin only or pre-mixed insulin in combination with oral and/or injectable (non-insulin) medications for at least 1 year prior to starting a FreeStyle Libre system
3. Has used a FreeStyle Libre system 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 a FreeStyle Libre system

5. HbA1c recorded in medical notes 3 to 6 months after starting a FreeStyle Libre system

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Has used bolus or basal insulin during the data collection period
2. Female participant who was pregnant during the data collection period
3. Received dialysis treatment during the data collection period
4. Participated in another medical device or drug study that, in the Investigator's opinion, could have affected glucose measurements or management during the data collection period

Date of first enrolment

15/01/2025

Date of final enrolment

30/06/2025

Locations

Countries of recruitment

United Kingdom

England

Wales

Study participating centre

Swansea Bay University LHB

Port Talbot

United Kingdom

SA12 7BR

Study participating centre
Cardiff & Vale University LHB
Cardiff
United Kingdom
CF14 4HH

Study participating centre
County Durham and Darlington FT
Darlington
United Kingdom
DL3 6HX

Study participating centre
Hywel Dda University LHB
St Davids Park
Carmarthen
United Kingdom
SA31 3BB

Study participating centre
Aneurin Bevan University LHB
Newport
United Kingdom
NP18 3XQ

Study participating centre
Middleton and Dinsdale Medical Practice
Darlington
United Kingdom
DL2 1BY

Study participating centre
Royal Glamorgan Hospital (CWM TAF MORG UNI LHB)
Llantrisant
United Kingdom
CF72 8TA

Sponsor information

Organisation

Abbott Diabetes Care

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 (pamela.reid@abbott.com).

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

IPD sharing plan summary

Available on request