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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

Registration date
27/01/2025

Overall study status
Completed

Last Edited
12/02/2025

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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

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Dr Pamela Reid

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
350006

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Retrospective chart review study

Study setting(s)
Medical and other records

Study type(s)
Other

Participant information sheet
Not applicable (retrospective study)

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

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/06/2024

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

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

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
England

United Kingdom

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

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Sponsor type
Industry

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
Possible presentation at a diabetes conference, and/or publication in a peer-reviewed journal. The estimated timeline is 1 year from the trial end date.

Intention to publish date
30/06/2026

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