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

Submission date
09/09/2022

Recruitment status
No longer recruiting

Registration date
03/10/2022

Overall study status
Completed

Last Edited
24/06/2025

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 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)
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Contact information

Type(s)

Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
312330

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Prevention

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

Key secondary outcome(s))
There are no secondary outcome measures

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

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

Northern Ireland

Scotland

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
Morriston 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

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
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?
Results article		04/08/2024	24/06/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes