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Masked performance check of the Abbott FreeStyle Libre Flash Glucose Monitoring System

Submission date
16/07/2015

Recruitment status
Recruiting

Registration date
17/08/2015

Overall study status
Ongoing

Last Edited
20/12/2023

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The FreeStyle Libre sensor automatically measures blood glucose levels around the clock, and stores the data for later retrieval. The aim of this study is to assess the accuracy of this device compared with blood glucose strips for patients with type 1 and type 2 diabetes.

Who can participate?
Patients aged at least 18 years with diabetes (type 1 or type 2).

What does the study involve?
All participants wear up to 3 masked FreeStyle Libre Flash Glucose Monitoring System for up to 14 days while going about their daily activities. That is, they wear the sensor according to labelling instructions but cannot see any sensor glucose data, unless they choose to wear an optional sensor (unmasked). The data collected is transferred and stored in the reader memory by regular scanning of the sensor by the participants. Participants also perform between four and eight fingerstick readings per day, using the built-in blood glucose test strip port in the device's reader. These blood glucose strip results are visible to the patient throughout. During visit 1 to their trial participating clinic, each participant's demographic data, height and weight is recorded and their HbA1c result obtained. Participants are then trained on how to use the FreeStyle Libre Flash Glucose Monitoring System and instructed to scan the sensor with the reader immediately after they do a fingerstick test. Three to five days later a follow-up phone call is made to check that participants have not had any issues. Participants return to the clinic on day 15 where their sensors are scanned prior to removal and the data uploaded. This is the end of their study participation. The data is subsequently analysed.

What are the possible benefits and risks of participating?
There may be no direct benefit to the participant by wearing the masked device. However, if the participant takes the option of wearing a second unmasked Sensor they can use this to manage their diabetes. Some participants may experience either mild or moderate symptoms associated

with the sensor placement on the skin as this is attached by means of a medical-grade adhesive. To minimize the risk of reactions, participants will be asked if they have a known allergy to medical grade adhesives prior to enrolment and checked at each visit.

Where is the study run from?
1. Ipswich Hospital NHS Trust (UK)
2. Oxford University Hospitals NHS Trust (UK)
3. North Manchester General Hospital, Crumpsall (UK)
4. The Royal United Hospital, Bath (UK)
5. The Royal Cornwall Hospital, Truro (UK)
6. St James Hospital, Leeds (UK)
7. St Georges Hospital (UK)
8. Frimley Park Hospital (UK)
9. Royal Surrey County Hospital (UK)
10. MAC Clinical Research Centre (UK)

When is the study starting and how long is it expected to run for?
July 2015 to March 2027

Who is funding the study?
Abbott Diabetes Care Ltd (UK)

Who is the main contact?
Dr Pamela Reid

Contact information

Type(s)
Public

Contact name
Dr Pamela Reid

Contact details
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
178494

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
ADC-UK-PMS-14021, IRAS 178494

Study information

Scientific Title
Masked performance check of the Abbott FreeStyle Libre Flash Glucose Monitoring System: an interventional trial

Study objectives
The aim of this study is to evaluate the accuracy and performance of the masked Abbott FreeStyle Libre Flash Glucose Monitoring System

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West - Lancaster, 20/03/2015, ref: 15/NW/0267

Study design
Multi-centre prospective single arm

Primary study design
Interventional

Secondary study design

Study setting(s)
Hospital, Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Diabetes mellitus

Interventions
Interventions as on 08/02/2017:
1. Participants will wear up to 3 Masked FreeStyle Libre Glucose Monitoring Sensor for up to 14 days. Participants have an option to experience the use ofan unmasked FreeStyle Libre Glucose Monitoring Sensor
2. Participants will also perform between 4 and 8 fingerstick readings per day for each day of sensor wear using the built-in test strip port

Original interventions section:
1. Participants will wear a Masked FreeStyle Libre Glucose Monitoring Sensor for 14 days, at the same time participants have an option to wear a second unmasked FreeStyle Libre Glucose Monitoring Sensor
2. Participants will also perform four fingerstick readings per day for each day of sensor wear using the built-in test strip port

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
FreeStyle Libre

Primary outcome measure
Accuracy performance of the Abbott FreeStyle Libre Flash Glucose Monitoring System compared to capillary fingerstick blood glucose values (FreeStyle Optium blood glucose test strips) using the consensus error grid.

Secondary outcome measures
Precision within Sensor lot.

Overall study start date
20/07/2015

Completion date
31/03/2027

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Have type 1 or type 2 diabetes
3. Be self-testing their blood glucose levels at least twice per day
4. Be able to follow the instructions provided to him/her by the study site and perform all study tasks as specified by the protocol, in the investigator’s opinion
5. Be available for all study visits
6. Be willing to provide written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
12 to 36 participants per sensor lot, with up to 12 sensor lots tested per study event

Key exclusion criteria
1. Participated in the same study event
2. Be a member of the study staff
3. Have a known allergy to medical grade adhesive
4. Be pregnant or planning to become pregnant within the study event duration
5. Have skin abnormality at the application sites
6. Have a pacemaker or any other neuro stimulators
7. Have concomitant medical condition which in the investigator’s opinion could interfere with the study or present a risk to the safety or welfare of the participant or study staff

Date of first enrolment
20/07/2015

Date of final enrolment
31/03/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Ipswich Hospital NHS Trust
Ipswich
United Kingdom
IP4 5PD

Study participating centre
Oxford University Hospitals NHS Trust
Oxford
United Kingdom
OX3 9DU

Study participating centre

North Manchester General Hospital
Delaunays Road
Crumpsall
Manchester
United Kingdom
M8 5RB

Study participating centre
Royal United Hospital Bath
Combe Park
Avon
Bath
United Kingdom
BA1 3NG

Study participating centre
Royal Cornwall Hospital
2 Penventinnie Lane
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Truro
United Kingdom
TR1 3LQ

Study participating centre
St James's University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
St George's University Hospital
Blackshaw Road
Tooting
London
United Kingdom
SW17 0QT

Study participating centre
Frimley Park Hospital
Portsmouth Road

Frimley
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GU16 7UJ

Study participating centre
Royal Surrey County Hospital
Egerton Road
Guildford
United Kingdom
GU2 7XX

Study participating centre
MAC Blackpool
1 Faraday Way
Blackpool
United Kingdom
FY2 0JH

Study participating centre
MAC Clinical Research Manchester
Citylabs 1.0
Nelson St
Manchester
United Kingdom
M13 9NQ

Study participating centre
MAC Clinical Research Teesside
Clinical Research Centre
Sabatier Close
Stockton-on-Tees
United Kingdom
TS17 6EW

Sponsor information

Organisation
Abbott Diabetes Care Ltd

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Sponsor type
Industry

ROR
https://ror.org/03wnay029

Funder(s)

Funder type
Industry

Funder Name
Abbott Diabetes Care Ltd

Results and Publications

Publication and dissemination plan
The primary device in the study is not being used in the same way as its on-market intended use, (i.e. the sensor results are masked to the subject). Therefore the findings from the study are of negligible value to the medical or scientific community and so it is challenging to publish. If the results highlight any interesting information we will consider specifically preparing a manuscript or abstract to report this.

Intention to publish date
31/03/2028

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No