ISRCTN17191485 https://doi.org/10.1186/ISRCTN17191485

User performance evaluation of the FreeStyle Optium Blood Glucose Monitoring System

Submission date
16/07/2015

Recruitment status
No longer recruiting

Registration date
17/08/2015

Overall study status
Completed

Last Edited
15/08/2022

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol
Background and study aims
The FreeStyle Optium Blood Glucose Monitoring System is a system for measuring glucose levels and is freely available to buy on the market in the UK. The aim of the study is to evaluate whether at least 95% of FreeStyle Optium Blood Glucose Monitoring System results are required to be within ± 0.83 mmol/L (15mg/dL) / 15%.of the YSI reference measurement.

Who can participate?
Patients with diabetes and aged at least 16 years.

What does the study involve?
Participants first have an opportunity to familiarise themselves with the FreeStyle Optium System, before performing a blood glucose test from their fingertip. A capillary blood sample is collected to perform haemoglobin testing on the HemoCue analyser and a glucose reference test on the YSI analyser. This should take up no more than 30 minutes of each participants time.

What are the possible benefits and risks of participating?
There is no direct benefit to the participant by taking part in this study. The only risks associated with the study are capillary blood sample collection, these are small but could include pain, bruising, local infection and fainting.
Where is the study run from?
The Ipswich Hospital NHS Trust and Leeds Teaching Hospitals NHS Trust (UK)

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

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
Range Road
Witney
United Kingdom
OX29 0YL

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ADC-UK-PES-15027

Study information

Scientific Title
User performance evaluation of the FreeStyle Optium Blood Glucose Monitoring System: a multi-centre prospective single arm study

Study objectives
The aim of the study is to evaluate whether at least 95% of FreeStyle Optium Blood Glucose Monitoring System results are required to be within ± 0.83 mmol/L (15mg/dL) / 15%.of the YSI reference measurement.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central - Berkshire B, 23/06/2015, ref: 15/SC/0395

Study design
Multi-centre prospective single arm

Primary study design
Interventional

Secondary study design

Study setting(s)

Other

Study type(s)
Prevention

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
1. A participant will perform a blood glucose measurement on the FreeStyle Optium Blood Glucose Monitoring System
2. A capillary blood sample will be collected to perform haemoglobin testing on the HemoCue analyser and a glucose reference test on the YSI analyser

Intervention Type
Device

Primary outcome measure
Accuracy analysis will be performed according to ISO 15197:2013 Section 8.2

The analysis will be performed when the study is complete. ISO 15197:20131 section 8.2 specifies that at least 95% of fingerstick blood glucose results are required to be within ± 0.83 mmol/L (15mg/dL) / 15% of the reference analyser (YSI). Regression analysis will also be performed and plots of the data will be generated.

Secondary outcome measures
Linear regression and error grid analysis.

Overall study start date
27/07/2015

Completion date
30/10/2015

Eligibility

Key inclusion criteria
1. Type 1 or Type 2 Diabetes
2. Age ≥ 16 years

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
120 participants

Total final enrolment
165

Key exclusion criteria
1. Currently using the FreeStyle Optium, Boots or Optium Xceed Blood Glucose Monitoring System for routine testing at home (as pictured in the PIIC)
2. Known to be infected with hepatitis B virus (Hep B), hepatitis C virus (Hep C) or human immunodeficiency virus (HIV)
3. Be a member of the study staff
4. Already participated in this study

Date of first enrolment
27/07/2015

Date of final enrolment
11/09/2015

Locations

Countries of recruitment
England

United Kingdom

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

Study participating centre
Leeds Teaching Hospitals NHS Trust
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation
Abbott Diabetes Care

Sponsor details
Range Road
Witney
United Kingdom
OX29 0YL

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
Results of these studies are rarely of interest to scientific or medical publications but we will submit to an appropriate journal or meeting in 2016.

Intention to publish date
01/07/2016

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Funder report results	Abbott white paper	01/01/2016	15/08/2022	No	No
HRA research summary			28/06/2023	No	No