

User performance evaluation of the FreeStyle Optium Blood Glucose Monitoring System

Submission date 16/07/2015	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol ☐ Statistical analysis plan ☒ Results ☐ Individual participant data
Registration date 17/08/2015	Overall study status Completed	
Last Edited 15/08/2022	Condition category Nutritional, Metabolic, Endocrine	

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

Protocol serial number

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

Primary study design

Interventional

Study design

Multi-centre prospective single arm

Study type(s)

Prevention

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(s)

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.

Key secondary outcome(s)

Linear regression and error grid analysis.

Completion date

30/10/2015

Eligibility

Key inclusion criteria

1. Type 1 or Type 2 Diabetes
2. Age ≥ 16 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

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

ROR

<https://ror.org/03wnay029>

Funder(s)

Funder type

Industry

Funder Name

Abbott Diabetes Care Ltd

Results and Publications

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