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Blood glucose performance test

Submission date	Recruitment status	[ ] Prospectively registered
17/11/2014	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/01/2015	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
09/07/2020	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The aim of this study is to monitor the performance of on-market (CE marked) blood glucose monitoring systems (blood glucose meters and test strips) designed for people with diabetes to test their blood glucose, especially those people who take insulin. These systems are used as part of standard care of diabetes and are freely available to buy on the market.

Who can participate?
Patients over 16 years of age with diabetes who are willing to provide a blood sample for analysis.

What does the study involve?
You will visit a diabetes clinic or suitable outpatient clinic. The visit is expected to last about 5 to 20 minutes. You will give a blood sample either by venepuncture (the puncture of a vein) or by a fingerprick and the blood will be tested using both the blood glucose monitoring system and the reference method.

What are the possible benefits and risks of participating?
There may be no direct benefit to the subject if they decide to take part in this study. However, the information gained from the results will make an important contribution to ensuring the blood glucose monitoring systems give reliable results for people with diabetes. The risks to taking part in this study are the same as those associated with routine self-blood glucose testing or giving a blood sample. These risks are small but could include pain, bruising, local infection and fainting caused by the lancet or needle used to obtain a blood sample.

Where is the study run from?
The Diabetes Centre, Ipswich Hospital NHS Trust (UK).

When is the study starting and how long is it expected to run for?
The study started in October 2014 and will finish in October 2024.

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

Who is the main contact?
Gerry Rayman

Contact information

Type(s)
Scientific

Contact name
Dr Gerry Rayman

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Additional identifiers

Protocol serial number
ADC-PMS-GLU-12014

Study information

Scientific Title
Blood glucose performance test

Acronym
NA

Study objectives
This aim of this study is to evaluate the accuracy of blood glucose monitoring systems on subjects with diabetes at the study site. The results will be evaluated by comparing results obtained using either venous whole blood obtained by venepuncture or capillary whole blood obtained from a fingerstick and then tested on the blood glucose monitoring system, to whole blood tested on the Yellow Spring Instrument (YSI analyser) reference method.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee East of England - Cambridge Central, 01/11/2013, REC ref: 13/EE/0258

Study design

Single-centre prospective open single-arm trial

Primary study design
Interventional

Study type(s)
Diagnostic

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

Interventions
Either:
Venepuncture will be performed and venous whole blood from the subject will be tested on the blood glucose monitoring system, the HemoCue analyser and the YSI analyser as whole blood
Or:
A fingerstick will be performed and capillary whole blood from the subject will be tested on the blood glucose monitoring system. The same fingerstick will be used to collect a blood sample to perform measurements on the HemoCue analyser and the YSI analyser as whole blood

Intervention Type
Device

Primary outcome(s)
The accuracy of the blood glucose monitoring system compared to the YSI analyser using fingerstick capillary or venous whole blood samples

Key secondary outcome(s))
N/A

Completion date
31/10/2024

Eligibility

Key inclusion criteria
1. Subjects has diabetes
2. Subject is willing to provide a whole blood sample for analysis using:
2.1. The blood glucose monitoring systems
2.2. HemoCue analyser
2.3. YSI analyser
3. The subject is able to understand the patient information sheet and sign the informed consent form prior to any clinical investigation plan directed activity

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 years

Sex
All

Key exclusion criteria
1. Subject under 16 years of age
2. Subject is unwilling or unable to give consent for a blood sample to be collected

Date of first enrolment
29/10/2014

Date of final enrolment
31/10/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Diabetes Centre
Ipswich Hospital
Heath Road
Ipswich
United Kingdom
IP4 5PD

Sponsor information

Organisation
Abbott Diabetes Care Ltd (UK)

ROR
https://ror.org/03wnay029

Funder(s)

Funder type
Industry

Funder Name
Abbott Diabetes Care Ltd (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

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