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Blood glucose performance test

Submission date	Recruitment status	[ ] Prospectively registered
10/02/2017	Recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/05/2017	Ongoing	[ ] 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
Diabetes is a lifelong condition that causes a person's blood sugar (glucose) level to become too high. The aim of this study is to monitor the performance of blood glucose monitoring systems (blood glucose meters and test strips) designed for people with diabetes to test their blood glucose.

Who can participate?
Patients aged 16 and over with diabetes

What does the study involve?
Participation for the patient consists of one visit to the study site. The visit is expected to last about 5 to 20 minutes. The participant gives a blood sample either by venepuncture (the puncture of a vein) or by a fingerprick and the blood is tested using both the blood glucose monitoring system and the reference method. The accuracy and precision of the methods are compared.

What are the possible benefits and risks of participating?
There may be no direct benefit to the participant taking part in this study. However, the information gained from the results ensures the blood glucose monitoring systems provide reliable results. The only risks of participating in this study are associated with blood sample collection. These are small but could include pain, bruising, local infection and fainting.

Where is the study run from?
1. Ipswich Hospital (UK)
2. Oxford Centre for Diabetes, Endocrinology and Metabolism (UK)
3. St James's University Hospital (UK)
4. Salford Royal Hospital (UK)
5. North Manchester General Hospital (UK)

When is the study starting and how long is it expected to run for?
February 2017 to December 2029 (updated 16/07/2019, previously: July 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ADC-UK-PMS-16030

Study information

Scientific Title
Blood glucose performance test: a multi-centre prospective single-arm study

Study objectives
Assess the accuracy of blood glucose monitoring systems using capillary blood samples according to ISO 15197 and venous blood samples using the Consensus Error Grid.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee: London – Westminster Research Ethics Committee, 22/12/2016, ref: 16/LO/2217

Study design
Multi-centre prospective single-arm study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

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

Interventions
Whole blood obtained from the subject (venous whole blood from venepuncture or capillary whole blood from a fingerstick) will be tested on the blood glucose monitoring systems, the HemoCue analyser and the YSI analyser.

Intervention Type
Device

Primary outcome measure
1. The accuracy of the blood glucose monitoring system compared to the YSI analyser using fingerstick capillary or venous whole blood samples:
1.1. Capillary: Percentage of replicates within ISO15197 2003 or 2015 system accuracy criteria
1.2. Venous: Percentage of responses within each zone of the Consensus Error Grid
Measured at the single study visit

Secondary outcome measures
1. Precision: Mean paired replicate coefficient of variation (Capillary/Venous)
2. Error grid analysis: Percentage of replicates within each zone of the Consensus Error Grid (Capillary)
Measured at the single study visit

Overall study start date
01/02/2017

Completion date
31/12/2029

Eligibility

Key inclusion criteria

1. Diagnosed with diabetes
2. ≥16 years of age

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
The target is to enroll approximately 55 participants per study event

Key exclusion criteria
1. Participated in the study event already
2. Member of the site study team

Date of first enrolment
01/02/2017

Date of final enrolment
31/12/2028

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Ipswich Hospital
United Kingdom
IP4 5PD

Study participating centre
Oxford Centre for Diabetes, Endocrinology and Metabolism
United Kingdom
OX3 7LE

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

Study participating centre
Salford Royal Hospital
United Kingdom
M6 8HD

Study participating centre
North Manchester General Hospital
United Kingdom
M8 5RB

Sponsor information

Organisation
Abbott Diabetes Care Ltd

Sponsor details
Range Road
Witney
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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
The purpose of this study is to monitor ongoing performance as part of a post-market surveillance program. Results are of limited interest to scientific or medical publications, however if the results highlight any interesting information a manuscript or abstract will be prepared.

Intention to publish date
31/12/2030

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

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