

Blood glucose performance test

Submission date 10/02/2017	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/05/2017	Overall study status Ongoing	<input type="checkbox"/> Protocol
Last Edited 09/07/2020	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Contact details
Range Road
Witney
United Kingdom
OX29 0YL
+44 (0)1993 863024
Pamela.reid@abbott.com

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
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

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