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Blood Ketone Performance Test

Submission date	Recruitment status	[_] Prospectively registered
21/02/2019	Recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/02/2019	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
15/04/2025	Nutritional, Metabolic, Endocrine	[X] 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 blood ketone monitoring systems (blood ketone meters and test strips) designed for people with diabetes to test their blood ketone levels.

Who can participate?
Patients aged 16 and over who are potentially ketotic

What does the study involve?
The participant will give a blood sample either by venepuncture (the puncture of a vein) or by a fingerprick and the blood will be tested on the blood ketone monitoring system as whole blood and on the reference method as plasma.

Participants can consent to give repeated blood samples until ketone levels return to normal. Participation in this study will cease prior to hospital discharge for participants providing samples at multiple time points.

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 ketone 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?
St James's University Hospital, Leeds, Salford Royal Hospital, Salford & North Manchester General Hospital, Manchester

When is the study starting and how long is it expected to run for?
January 2016 to September 2035

Who is funding the study?
The study is funded by Abbott Diabetes Care Ltd

Who is the main contact?
Dr Pamela Reid
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Contact information

Type(s)
Public

Contact name
Dr Pamela Reid

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
142273

Protocol serial number
PMS-KET-004

Study information

Scientific Title
Blood Ketone Performance Test

Study objectives
Current study hypothesis as of 15/04/2025:
To collect data from blood ketone monitoring systems by comparing whole blood results obtained using the blood ketone monitoring system to plasma measurements obtained by a laboratory reference method.

Previous study hypothesis:
Assess the accuracy of blood ketone monitoring systems by comparing results to plasma measurements obtained by a laboratory reference method.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 03/01/2016, North West – Greater Manchester (GM) East Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 (0) 2071048290; gmeast.rec@hra.nhs.uk), ref: 04/Q1401/15

Study design
Multi-centre open-label prospective single arm

Primary study design
Other

Study type(s)
Other

Health condition(s) or problem(s) studied
Patients with potential ketosis, including diabetes patients and those presenting with diabetic ketoacidosis (DKA)

Interventions
Current interventions as of 15/04/2025:
Participants will provide a venous or capillary blood sample that will be tested on the blood ketone monitoring system/s. Participants, particularly those with DKA, can continue to provide samples until their ketone levels return to normal levels. For any inpatients, participation will cease prior to hospital discharge.

Previous interventions:
Participants will provide a venous or capillary blood sample that will be tested on the blood ketone monitoring system until their ketone levels return to normal levels. For any in-patients, participation will cease prior to hospital discharge.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Blood ketone monitoring systems

Primary outcome(s)
Current primary outcome measure as of 15/04/2025:
The results from blood ketone monitoring systems will be compared to plasma measurements obtained by a laboratory reference method using Bland-Altman analysis.

Previous primary outcome measure:
The accuracy performance of the blood ketone monitoring system compared to plasma measurements obtained by a laboratory reference method by using the Bland-Altman plot.

Key secondary outcome(s))
Blood samples will be used to compare results obtained on the blood ketone monitoring systems (y) with plasma results obtained on the reference system (x) by performing linear

regression analysis (y vs. x). The slope, intercept, correlation coefficient, and confidence intervals for the slope and intercept will be calculated.

Completion date
30/09/2035

Eligibility

Key inclusion criteria
1. Any potentially ketotic person.
2. ≥16 years of age.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 years

Sex
All

Key exclusion criteria
1. Known to be infected with hepatitis B virus (Hep B), hepatitis C virus (Hep C) or human immunodeficiency virus (HIV).
2. Member of the study staff.

Date of first enrolment
18/04/2016

Date of final enrolment
30/09/2035

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St James's University Hospital
Leeds

United Kingdom
LS9 7TF

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

Sponsor information

Organisation
Abbott Diabetes Care Ltd

Funder(s)

Funder type
Industry

Funder Name
Abbott Diabetes Care Ltd

Results and Publications

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

IPD sharing plan summary
Available on request