

Blood Ketone Performance Test

Submission date 21/02/2019	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered
Registration date 28/02/2019	Overall study status Ongoing	<input type="checkbox"/> Protocol
Last Edited 15/04/2025	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> 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
Pamela.reid@abbott.com

Contact information

Type(s)

Public

Contact name

Dr Pamela Reid

Contact details

Range Road, Witney
Witney
United Kingdom
OX29 0YL
Range Road, Witney
Pamela.reid@abbott.com

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

142273

ClinicalTrials.gov (NCT)

Nil known

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