

Laboratory evaluation of β -hydroxybutyrate levels in capillary and venous blood

Submission date 13/12/2019	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/12/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 21/11/2024	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Diabetic ketoacidosis (DKA) is a potentially life-threatening complication of diabetes mellitus. DKA is typically diagnosed when testing finds high blood sugar, low blood pH and ketones (including β -hydroxybutyrate) in either the blood or urine. Ketones are substances that your body makes if your cells don't get enough glucose (blood sugar).

The aim of this study is to evaluate the difference between blood β -hydroxybutyrate levels in blood that is flowing away from the heart and flowing towards the heart (after it has passed through tissues).

Who can participate?

Patients aged 16 and over who are potentially ketotic.

What does the study involve?

The participant will give a blood sample by venepuncture (the puncture of a vein) or by a fingerprick and the blood will be tested on the reference method as plasma.

Participants can give a maximum of four blood samples until ketone levels return to normal. Participation in this study will cease prior to hospital discharge.

What are the possible benefits & risks of participating?

There is no direct benefit to the participant taking part in this study. 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. John Radcliffe Hospital, Oxford, UK
2. Royal Surrey County Hospital, Guildford, UK
3. Royal United Hospitals, Bath, UK
4. Royal Cornwall Hospital, Truro, UK
5. Royal Infirmary, Edinburgh, UK

When is the study starting and how long is it expected to run for?

September 2019 to September 2020

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

Who is the main contact?
Dr Pamela Reid
Pamela.Reid@abbott.com

Contact information

Type(s)
Public

Contact name
Dr Pamela Reid

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Additional identifiers

Integrated Research Application System (IRAS)
275338

Protocol serial number
ADC-UK-RES-19045

Study information

Scientific Title
Laboratory evaluation of β -hydroxybutyrate levels in capillary and venous blood

Study objectives
This study is being conducted to determine the difference in β -hydroxybutyrate levels in capillary and venous blood, sampled concurrently from people in diabetic ketoacidosis (DKA) or with ketosis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/11/2019, NRES Committee: London - City & East Research Ethics Committee (Bristol Research Ethics Committee Centre, Whitefriars, Level 3, Block B, Lewins Mead, Bristol, BS1 2NT; +44 (0)207 104 8033; nrescommittee.london-cityandeast@nhs.net), ref: 19/LO/1919

Study design

Prospective multi-centre single-arm study in hospital settings

Primary study design

Observational

Study type(s)

Other

Health condition(s) or problem(s) studied

Diabetic ketoacidosis or ketosis

Interventions

Participants will have venous and capillary blood collected, which may be repeated:

- A maximum of 4 times
- Or, until ketone levels return to normal
- Or, participants are discharged from hospital

Intervention Type

Other

Primary outcome(s)

Capillary blood β -hydroxybutyrate levels and venous blood β -hydroxybutyrate levels as measured on the Randox Ranbut laboratory reference method using Bland-Altman analysis at each visit

Key secondary outcome(s)

None

Completion date

30/09/2020

Eligibility**Key inclusion criteria**

1. Aged 16 years or over
2. Potentially ketotic, or in diabetic ketoacidosis

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Already participated in this study
2. Concomitant medical condition which in the investigator's opinion could interfere with the study or present a risk to the safety or welfare of the participant or study staff
3. Infected with hepatitis B virus (Hep B), hepatitis C virus (Hep C), or human immunodeficiency virus (HIV)

Date of first enrolment

06/01/2020

Date of final enrolment

30/09/2020

Locations

Countries of recruitment

United Kingdom

England

Scotland

Study participating centre

John Radcliffe Hospital

Oxford

United Kingdom

OX3 9DU

Study participating centre

Royal Surrey County Hospital

Guildford

United Kingdom

GU2 7XX

Study participating centre

Royal United Hospitals

Bath

United Kingdom

BA1 3NG

Study participating centre

Royal Cornwall Hospital

Truro

United Kingdom
TR1 3LJ

Study participating centre
Royal Infirmary
Edinburgh
United Kingdom
EH16 4TJ

Sponsor information

Organisation
Abbott (United Kingdom)

ROR
<https://ror.org/03wnay029>

Funder(s)

Funder type
Industry

Funder Name
Abbott Diabetes Care

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the study will be available upon request from Pamela Reid (Pamela.Reid@abbott.com).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			21/11/2024	No	No
HRA research summary			28/06/2023	No	No