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

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
13/12/2019		☐ Protocol		
Registration date 20/12/2019	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited 21/11/2024	Condition category Nutritional, Metabolic, Endocrine	[] 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

Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

275338

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

ADC-UK-RES-19045; IRAS 275338

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

Secondary study design

Epidemiological study

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

No participant information sheet available

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 measure

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

Secondary outcome measures

None

Overall study start date

01/09/2019

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

Age group

Adult

Sex

Both

Target number of participants

35

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

England

Scotland

United Kingdom

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)

Sponsor details

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

Sponsor type

Industry

Website

http://www.abbott.co.uk/

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

Publication and dissemination plan

Possible presentation at a diabetes conference, and/or publication in a peer-reviewed journal. Estimated timeline is one year from trial end date.

Intention to publish date

30/09/2021

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?
HRA research summary			28/06/2023	No	No
Basic results			21/11/2024	No	No