ISRCTN31042751 https://doi.org/10.1186/ISRCTN31042751

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

Submission date
13/12/2019

Recruitment status
No longer recruiting

Registration date
20/12/2019

Overall study status
Completed

Last Edited
21/11/2024

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
Range Road
Witney
United Kingdom
OX29 0YL
+44 (0)1993 863024
Pamela.Reid@abbott.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
275338

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes