ISRCTN15351917 https://doi.org/10.1186/ISRCTN15351917

Effect of COVID-19 on diabetes in Black Asian and Minority Ethnic (BAME) patients

Submission date
17/05/2021

Recruitment status
Stopped

Registration date
01/07/2021

Overall study status
Stopped

Last Edited
10/01/2022

Condition category
Nutritional, Metabolic, Endocrine

- [ ] Prospectively registered
- [ ] Protocol
- [ ] Statistical analysis plan
- [ ] Results
- [ ] Individual participant data
- [ ] Record updated in last year

Plain English summary of protocol

Background and study aims
People of Black, Asian or Minority Ethnic (BAME) backgrounds are found to have a two to three times higher risk of death from COVID-19 compared with the population as a whole. COVID-19 infection enters the pancreas and may cause damage that reduces insulin production. This may worsen diabetes control and may even induce new-onset diabetes. This study aims to measure blood sugar control in the participants to find out whether there is a relationship between COVID-19 infection and diabetes in the BAME population. The researchers will also study whether there was a worsening of the body mass index, kidney function, blood pressure, lipid profile and urine protein loss. These are all linked to diabetes control. People with diabetes experience disproportionately high rates of mental health problems such as depression, anxiety and eating disorders. During the COVID-19 pandemic worsening of these aspects may have led to worsening of diabetes control. As a secondary aim, the researchers plan to study these effects using a psychologist-developed questionnaire.

Who can participate?
Patients aged 18 years and above who are from the BAME community with diabetes who contracted COVID-19 infection, or new-onset diabetes after contracting COVID-19 infection

What does the study involve?
The study involves identifying eligible patients and contacting them by mail to participate in the study. They will be mailed information about the study and if they consent to participation, they will sign the consent form. They can withdraw consent at any time. Participants will then be invited for a health screening assessment at Darent Valley Hospital or at their GP practice. The assessment involves checking their height, weight, blood and urine tests. If they have had recent screening as part of their routine diabetes care, the researchers will ask for access to this data. Participants will also be asked to complete a questionnaire to assess factors that could affect diabetes control.

What are the possible benefits and risks of participating?
The potential benefits are the possibility of detecting an undiagnosed health condition - the participants' GPs will be informed of test results and early treatment can be started. Measurement of height, weight, blood pressure, blood tests for HbA1c, lipid profile, kidney

function and urine albumin creatinine ratio are done as part of usual diabetes care. However, there has been no specific focus on the effects of COVID-19 infection on these measurements. By doing this study, the researchers will take a closer look at their diabetes care and improve it if necessary. Potential risks include discomfort from the blood sampling - a professional with phlebotomy training/experience will conduct all blood tests. The questionnaire may be psychologically and emotionally challenging but was approved by a psychologist to ensure minimum disruption to the participant. The participant is able to withdraw at any time.

Where is the study run from?
Darent Valley Hospital (UK)

When is the study starting and how long is it expected to run for?
November 2020 to November 2021

Who is funding the study?
Valley Hospital Charity (UK)

Who is the main contact?
Dr Cynthia Mohandas
c.mohandas@nhs.net

Contact information

Type(s)
Scientific

Contact name
Dr Cynthia Mohandas

Contact details
Darent Valley Hospital
Darenth Wood Road
Dartford
United Kingdom
DA2 8DA
+44 (0)7871922423
c.mohandas@nhs.net

Type(s)
Public

Contact name
Miss Rajdeep Heire

Contact details
Darent Valley Hospital
Darenth Wood Road
Dartford
United Kingdom

DA2 8DA
+44 (0)7947752111
rajdeep.heire@nhs.net

Type(s)
Public

Contact name
Dr Rajiv Singh

ORCID ID
https://orcid.org/0000-0003-3288-6347

Contact details
Darent Valley Hospital
Darenth Wood Road
Dartford
United Kingdom
DA2 8DA
+44 (0)7402592979
rajiv.singh5@nhs.net

Additional identifiers

Integrated Research Application System (IRAS)
296707

Study information

Scientific Title
Impact of COVID-19 on staff and patients from the Black Asian and Minority Ethnic (BAME) community with diabetes

Acronym
DDBC

Study objectives
The primary objective is to understand the glycaemic effect of COVID-19 infection on BAME (Black Asian and Minority Ethnic) patients with known diabetes or new-onset diabetes. The researchers expect at least 10 mmol/mol deterioration in their HbA1c.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/11/2020, Darent Valley Hospital Research and Development Department (Darent Valley Hospital, Darenth Wood Road, DA2 8DA, UK; +44 (0)1322428256; dgn-tr.fundraising@nhs.net), ref: not applicable

Study design

Single-centre longitudinal observational study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Impact of COVID-19 (SARS-CoV-2 infection) on diabetes in the BAME population

Interventions
Patients will be identified from the researchers' database (from Business Intelligence and Occupational Health) by applying inclusion and exclusion criteria. They will be invited to participate in the study via letter and will be mailed the Participant Information Sheet and Consent Form. If they consent they will be mailed a psychosocial questionnaire.

If they consent to participate, they will be invited for a Health Screening Assessment Visit. Participants will be instructed to attend Darent Valley Hospital Diabetes Centre, their GP surgery or a virtual telephone appointment if recent health records with pertinent data are available.
The screening visit will start with receiving informed consent from the participants, followed by:
1. Physical parameters: height, weight and blood pressure measurements
2. Blood tests: HbA1c, lipid profile, renal function
3. Urine sample: urinary albumin creatinine ratio
4. Patients can hand in their completed psychosocial questionnaire or complete the questionnaire

Intervention Type
Other

Primary outcome(s)
Glycated haemoglobin (HbA1c) measured using blood test pre and post COVID-19 infection within 12 months

Key secondary outcome(s))
1. Body mass index measured using BMI calculator pre and post COVID-19 infection within 12 months
2. Renal function measured using blood test pre and post COVID-19 infection within 12 months
3. Blood pressure measured using calibrated blood pressure machine pre and post COVID-19 infection within 12 months
4. Lipid profile measured using blood test pre and post COVID-19 infection within 12 months
5. Proteinuria measured using urine sample pre and post COVID-19 infection within 12 months
6. Depression, anxiety and eating disorders measured using a psychologist-developed questionnaire (Diabetes and COVID-19 Participant Questionnaire Booklet) post COVID-19 infection within 12 months

Completion date
16/11/2021

Reason abandoned (if study stopped)

Did not receive ethics approval

Eligibility

Key inclusion criteria
1. 18 years and above
2. Identifies as Black, Asian or Minority Ethnic (BAME)
3. Diagnosed COVID-19 with viral PCR nasal swab in hospital or community
4. Diagnosed type 1 or type 2 diabetes mellitus (T1DM or T2DM, according to WHO criteria) prior to or after COVID-19 diagnosis
5. Able to provide informed consent and willing to participate in the study and follow the instructions

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. From any other demographic not in the BAME group
2. Not confirmed COVID-19 with viral PCR nasal swab in hospital or community
3. Not confirmed T1DM or T2DM according to WHO criteria
4. Unwilling/unable to participate or comply with the protocol

Date of first enrolment
31/05/2021

Date of final enrolment
30/09/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Darent Valley Hospital
Darenth Wood Road
Dartford
United Kingdom
DA2 8DA

Sponsor information

Organisation
Darent Valley Hospital

ROR
https://ror.org/001m5qg34

Funder(s)

Funder type
Charity

Funder Name
The Valley Hospital Charity

Results and Publications

Individual participant data (IPD) sharing plan
Data will only be shared within the research team. Data will be managed according to the Data Protection Act 2018, NHS Caldicott Guardian and the Research Governance Framework for Health and Social Care. The Principal Investigator will be the Custodian of all trial data. Written consent will be obtained from participants. Participant data will be pseudo-anonymised and stored on a password-protected computer. Data will be anonymised for any publications relating to this study.

IPD sharing plan summary
Not expected to be made available