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Long term effects of COVID-19 in people with diabetes

Submission date
20/05/2021

Recruitment status
No longer recruiting

Registration date
24/05/2021

Overall study status
Completed

Last Edited
10/02/2023

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
People with diabetes have suffered greater adverse consequences of COVID-19 in the acute phase of infection during the pandemic. Whether they also have increased susceptibility to longer term sequelae is unknown. Such knowledge is critical to public health approaches to management of the pandemic in these populations. We will build on the excellent available surveillance of the population of people with diabetes in Scotland using the existing sci-diabetes platform, used already to accurately detail short-term outcomes.
Current research during the COVID crisis has highlighted that to the end of July, 2,724 people with diabetes had covid-19 (positive test, admission, or death certificate) of whom 988 had unfortunately died. This means more than 1,736 people with diabetes in Scotland may be living with the consequences of Covid-19. Assessment of the long term holistic impact on people with diabetes cannot be approached using routine data collated from electronic health records and so we propose to use the resources of the Scottish Diabetes Research Network (SDRN) to collect information through questionnaires and clinical examination on a range of outcomes in people with diabetes compared to the general population of people with diabetes.

Who can participate?
People aged over 18 resident in Scotland and with prior diagnosis of type 1 or type 2 diabetes

What does the study involve?
All participants will complete 4 questionnaires online. A smaller group of these participants will also be asked for a blood sample and to take some physical tests during a hospital visit, and repeat these measures after one year.

What are the possible benefits and risks of participating?
The study will not benefit you directly, but your participation will help provide important information about the impact of COVID-19 infection on diabetes patients and provide a stronger evidence base to inform national guidance and policy.
A possible benefit to you might be that if you've had COVID without realising it, we will be able to inform you of this.
For some, blood sampling may cause momentary discomfort at the site of the blood draw, possible bruising, redness, and swelling around the site, bleeding at the site, feeling of light

headedness when the blood is drawn, and rarely, an infection at the site of blood draw.
There are some risks from the walking test such as tripping, falling, exhaustion and fatigue. A research staff member will be present to offer one:one support and the walk test will be carried out in a wide corridor free of trip hazards and obstructions. You will be able to use a walking aid if you routinely use one.
Lung function tests (spirometry) require the use of a mouthpiece connected to the device which poses a risk of infection. To minimise risk, mouthpiece plastic is single use and you'll be shown how to carry out the test correctly.

Where is the study run from?
University of Glasgow (UK)

When is the study starting and how long is it expected to run for?
November 2020 to October 2024

Who is funding the study?
Chief Scientist Office, Scottish Government Health and Social Care Directorate (UK)

Who is the main contact?
Dr Robert Lindsay, robert.lindsay@glasgow.ac.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
297448

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Sponsor ID GN20DI579_313445, IRAS 297448

Study information

Scientific Title
Longer term impact of COVID infection in people with diabetes

Study objectives
To understand the proportion of people with diabetes who experience longer term symptoms or illness after covid-19 infection, the nature of these symptoms, and the potential health impact of that.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/05/2021, South East Scotland Research Ethics Committee 1(2ndFloor, Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG, UK; +44 (0)7814 764 241; Sandra.Wyllie@nhslothian.scot.nhs.uk), ref: 21/SS/0040

Study design
Case cohort and nested case control studies

Primary study design
Observational

Secondary study design
Nested case-control study

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection) in people with diabetes

Interventions
Observational study with current health measured by questionnaire, bioimpedance, pulmonary function, grip strength, walking test.

1. Case cohort study - conducted with questionnaire usually online. Time from enrolment to end of this part of study is 1 hour . For the majority of participants this will be their only participation.

2. Case control study - people are recruited from the case cohort study and involves :
2.1. For controls single CRF visit (time 1 hours) - no in person follow up after this
2.2. Cases 2 CRF visits separated by up to 64 weeks later but each visit only 1 hour: total follow up to 64 weeks

For all participants we will request permission to connect data to their electronic health record but no other in person follow up

Intervention Type
Mixed

Primary outcome measure
COVID symptoms measured using Wellcome Trust COVID-19 questionnaire at baseline (all participants) and 1 year (cases only)

Secondary outcome measures
Measured at baseline (all participants in case cohort study) and 1 year (cases in case cohort study only)
1. Bioimpedance measured using bioelectrical impedance analysis
2. Pulmonary function measured using lung function test
3. Grip strength measured using dynamometer
4. Physical ability measured using walking test
5. Diabetes Related Quality of Life (DQOL)
6. Diabetes-Specific Emotional Distress (DDS-1)
7. Quality of life (EQ5D)
8. HbA1c, LFTs, lipids, U&Es, inflammatory (e.g. CRP), vascular (t-PA, vWF) and cardiac (hs troponin, NT proBNP) biomarkers measured using blood test

Overall study start date
01/11/2020

Completion date
31/10/2024

Eligibility

Key inclusion criteria
People aged over 18 resident in Scotland and with prior diagnosis of type 1 or type 2 diabetes

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1,000 in case control part

Key exclusion criteria
Not able to read and write in English

Date of first enrolment
28/05/2021

Date of final enrolment
28/02/2024

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
University of Glasgow
126 University Place
Glasgow
United Kingdom
G12 8TA

Sponsor information

Organisation
NHS Greater Glasgow and Clyde

Sponsor details
R&I Office
Ward 11, Dykebar Hospital
Grahamston Road
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+44 (0)141 314 4012
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Sponsor type
Hospital/treatment centre

Website
http://www.nhsggc.org.uk/

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office, Scottish Government Health and Social Care Directorate

Alternative Name(s)
Chief Scientist Office, Scottish Government Health Directorate CSO, Chief Scientist Office, Scottish Government Health Directorates, Chief Scientist Office of the Scottish Government Health Directorates, Scottish Government Health and Social Care Directorate of the Chief Scientist Office, Scottish Government Health Directorate Chief Scientist Office, The Chief Scientist Office, CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The study report will be used for publication and presentation at scientific meetings. Investigators have the right to publish orally or in writing the results of the study. Summaries of results will also be made available to Investigators for dissemination within their clinical areas (where appropriate and according to their discretion).

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository: the ENLIGHTEN database of the University of Glasgow. Data stripped of all personal identifiers will be stored for 10 years and made available to bona fide

researchers after the end of the study and study data analysis . Details of this data storage and sharing are transmitted to participants on the PIS for each part of the study.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version v1.0	24/03/2021	01/06/2021	No	No