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Development of a risk prediction model for people with diabetes and COVID-19 in Scotland

Submission date
16/10/2020

Recruitment status
No longer recruiting

Registration date
19/10/2020

Overall study status
Completed

Last Edited
05/10/2022

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
COVID-19 is a condition caused by the coronavirus (called SARS-CoV-2) that was first identified in late 2019. This virus can infect the respiratory (breathing) system. Some people do not have symptoms but can carry the virus and pass it on to others. People who have developed the condition may develop a fever and/or a continuous cough among other symptoms. This can develop into pneumonia. Pneumonia is a chest infection where the small air pockets of the lungs, called alveoli, fill with liquid and make it more difficult to breathe.

In 2020, the virus has spread to many countries around the world and neither a vaccine against the virus or specific treatment for COVID-19 has yet been developed. As of March 2020, it is advised that people minimize travel and social contact, and regularly wash their hands to reduce the spread of the virus.

Groups who are at a higher risk from infection with the virus, and therefore of developing COVID-19, include people aged over 70 years, people who have long-term health conditions (such as asthma or diabetes), people who have a weakened immune system and people who are pregnant. People in these groups, and people who might come into contact with them, can reduce this risk by following the up-to-date advice to reduce the spread of the virus.

There is very little known amount the risk factors among those with diabetes that contribute to risk of COVID-19. This study aims to understand the risks of and risk factors for COVID-19 in people with diabetes

Who can participate?
People living with or without diabetes in Scotland with COVID-19

What does the study involve?
Health records of people with COVID-19 will be compared to records of people with and without diabetes to find risk factors that contribute to death with COVID-19 in diabetes patients.

What are the possible benefits and risks of participating?
None

Where is the study run from?
Public Health Scotland (UK)

When is the study starting and how long is it expected to run for?
April 2020 to July 2020

Who is funding the study?
Public Health Scotland (UK)

Who is the main contact?
Professor Helen Colhoun, helen.colhoun@igmm.ed.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
PBPP ref. 1617- 0147

Study information

Scientific Title

Risk of and risk factors for fatal or critical care unit treated COVID-19 and development of a risk prediction model in people with diabetes in Scotland: A cohort study

Study objectives
Objectives:
1. Ascertain the cumulative risk of fatal or CCU treated COVID -19 in those with diabetes and compare it to those without diabetes
2. Among those with diabetes to investigate risk factors for, and build a cross-validated predictive model of, fatal or CCU treated COVID-19

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 06/04/2020, Public Benefit Privacy Protection Panel Scotland (no address provided; no telephone number provided; phs.pbpp@nhs.net), PBPP ref. 1617- 0147
2. Approved 01/06/2011, Scotland A Research Ethics Committee (2nd Floor Waverly Gate 2-4 Waterloo Place, Edinburgh, EH1 3EG, UK; +44 (0)131 465 5680; Manx.Neill@nhslothian.scot.nhs.uk), ref: 11/AL/0225

Study design
Observational cohort

Primary study design
Observational

Study type(s)
Other

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

Interventions
In the total population of Scotland (5.6 million) we will ascertain all persons who had developed fatal or critical care unit-treated COVID-19 (hereafter F/CCU-COVID-19) between 1st March and July 31st 2020 from the nationwide virology, critical care unit, hospital discharge and register of deaths databases. Among those with F/CCU-COVID-19, diabetes status will be ascertained by linkage to the national diabetes register. The cumulative incidence of F/CCU-COVID-19 in those with and without diabetes will be compared using logistic regression. Among those with diabetes, data on potential risk factors for F/CCU-COVID-19 will be obtained from diabetes register and other linked health administrative databases. Among those with diabetes we will test association of these factors with F/CCU-COVID-19 and construct a prediction model using stepwise regression and 20-fold cross-validation.

Intervention Type
Not Specified

Primary outcome(s)
Fatal of Critical care Unit COVID-19 defined with cases ascertained on the basis of positive rtPCR test, hospital admission and death certification and this level of severity defined using linkage to

the national critical care unit database (SICSAG) and death certification data (types of information included laboratory test results, ICD10 codes for hospital discharge diagnoses, dates of entry into critical care units and cause of death on death certificates)

Key secondary outcome(s))
None

Completion date
31/07/2020

Eligibility

Key inclusion criteria
People of any age living with or without diabetes in Scotland

Participant type(s)
All

Healthy volunteers allowed
No

Age group
All

Sex
All

Total final enrolment
5782649

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/03/2020

Date of final enrolment
31/07/2020

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre

Public Health Scotland
Meridian Court
5 Cadogan Street
Glasgow
United Kingdom
G2 6QE

Sponsor information

Organisation
Health Protection Scotland

ROR
https://ror.org/04zgkpa58

Funder(s)

Funder type
Government

Funder Name
Public Health Scotland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the Scottish Public Benefits and Privacy Protection Committee

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/02/2021	25/03/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			05/10/2022	No	No