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A long-term observational study of people who have had coronavirus disease (COVID-19) in Scotland

Submission date
22/10/2020

Recruitment status
No longer recruiting

Registration date
05/03/2021

Overall study status
Ongoing

Last Edited
06/04/2021

Condition category
Infections and Infestations

[_] 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:
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.

Severe COVID-19 infection can cause severe pneumonia and acute respiratory distress syndrome (ARDS) leading to a requirement for mechanical ventilation. It is also now recognised that it can cause inflammation of blood vessels which may lead to a longer term increased risk of cardiovascular disease. NHS Scotland must plan for the long term care of potentially thousands of patients who will experience long term complications of COVID-19, both within the lung and outside the lung. As COVID19 is a new disease, there is a need to identify the long term consequences and future care needs of COVID19 survivors.

Who can participate?
We wish to establish a national cohort of 300 people over the age of 18 years who have had COVID19, either as hospital inpatients or in the community.

What does the study involve?
In this study, blood testing, urine, respiratory samples, and tests of blood vessel function will be used to help determine the long term consequences of this disease and identify future management approaches. This will be through the current study and in the future with analysis of healthcare use.
Specific interests will include the recovering epithelial function in the lungs; endothelial function relating to cardiovascular disease and diabetes; effects of COVID-19 on complications related to, and management of diabetes; characterising the microbiome of the airway epithelium after COVID-19; development of a biobank of samples to further research predictors of long term health outcomes; long term assessment of healthcare use following COVID disease.

What are the possible benefits and risks of taking part?
There is no direct benefit to participants as this study will not directly change the clinical care that they receive. The information that is collected may help clinicians to better care for other patients in the future. If there are any test results that require follow-up, the participant and their doctor will be informed.

Whenever possible any study samples will be taken at the same time as regular samples to reduce the extra procedures. There is a risk of discomfort when samples are taken, and this is detailed in the participant information sheet.

Where is the study run from?
From NHS Tayside (UK) and will recruit participants from multiple sites across Scotland.

When is the study starting and how long is it expected to run?
From June 2020 to December 2046.

Who is funding the study?
The study is funded by Chief Scientist Office, Scottish Government (UK) and the British Lung Foundation (UK)

Who is the main contact?
Dr David Connell, Chief Investigator
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
284116

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 284116

Study information

Scientific Title
FOcused LongitudinaL Observational study to improve knoWledge of COVID-19 (FOLLOW-COVID)

Acronym
FOLLOW-COVID

Study objectives
1. To describe the consequences of COVID-19, on the airway epithelial microbiome, and on longitudinal lung epithelial and vascular function, in a cohort of patients who have had a spectrum of disease as a result of infection with SARS-CoV-2
2. To describe neutrophil function in survivors of severe COVID-19 pneumonia
3. To generate a biobank of samples from patients who are recovering from COVID-19, which can later be used to identify and predict recovery from severe COVID-19 across a range of health domains, including diabetes
4. To determine long term healthcare resource utilisation in patients who have had COVID-19 disease

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 16/09/2020, Yorkshire and The Humber - South Yorkshire Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle, HE2 4NQ, UK: +44 (0)207 1048091; southyorks.rec@hra.nhs.uk), ref 20/YH/0265

Study design
Multi-centre prospective observational longitudinal study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Other

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

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

Interventions
FOLLOW-COVID is an observational longitudinal follow-up study of adults with COVID-19. The researchers propose to analyse routine clinical data with linkage to retrospective and prospective health and social care records with research-specific biosampling.

All participants will be seen at two study visits, 3-6 months post-COVID-19 infection, at which samples will be obtained, then followed up by telephone at years 1, 2, and 5. The researchers will ask participants for their agreement to continue to extract data from their electronic records, and to be contacted about future research, for up to 25 years after recruitment to the study.

Intervention Type
Other

Primary outcome measure
1. A description of the early longitudinal changes in the airway epithelial microbiome and mycobiome using radiological and clinical note review at 3-6 months post-COVID-19
2. Recovery of symptoms post-COVID as self-defined by the patient at 3-6 months post-COVID-19

Secondary outcome measures
1. A detailed description of the early (3-6 months) regenerating ultrastructural changes in the nasal airway epithelium measured using a combination of video microscopy, electron microscopy, and cell culture techniques, in a spectrum of patients recovering from COVID-19 at

3-6 months post-COVID-19
2. Assessments of microvascular and macrovascular endothelial function, arterial stiffness, vascular inflammation, and fat metabolites in the 3-6 months following severe and non-severe COVID-19 measured using non-invasive techniques; these can be linked to inflammatory intravascular gene expression in PBMCs and whole blood; at 3-6 months post-COVID-19
3. A description of neutrophil function in patients recovering from severe COVID-19 pneumonia, including those with ARDS using radiological and clinical note review at 3-6 months post-COVID-19
4. Linking with the SCI-Diabetes database to obtain a comprehensive analysis of the impact of COVID-19 on diabetes care in affected patients and linking this to changes in serum metabolic biomarkers obtained 3-6 months following COVID-19
5. Long-term assessment of healthcare utilisation measured using electronically linked health care records, and phone interviews, and linking these outcomes with the work streams described above, and with biomarker discovery from stored samples, initially over 5 years and up to 25 years

Overall study start date
01/06/2020

Completion date
31/12/2046

Eligibility

Key inclusion criteria
1. Previous clinical (only if hospitalised) or microbiological (if hospitalised or non-hospitalised) diagnosis of COVID-19 disease
2. Aged >18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
300

Key exclusion criteria
1. Unable to give informed consent
2. Participation is not in the interests of the patient as determined by the investigator (e.g. palliative care)
3. If an individual has any symptoms compatible with current COVID-19 (as per the Health Protection Scotland Guidelines relevant at that time)

4. Currently isolated following a contact with COVID-19
5. Has had an upper respiratory tract infection in the preceding 14 days
6. Nasal brushings only: Patient has a history of significant epistaxis or is anti-coagulated

Date of first enrolment
13/10/2020

Date of final enrolment
31/01/2021

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
NHS Tayside
Kings Cross
Clepington Road
Dundee
United Kingdom
DD1 9SY

Study participating centre
NHS Fife
Springfield House
Cupar
United Kingdom
KY15 5UP

Study participating centre
NHS Lanarkshire
14 Beckford Street
Hamilton
United Kingdom
ML3 0TA

Study participating centre
NHS Highland
Reay House
17 Old Edinburgh Road

Inverness
United Kingdom
IV2 3HG

Study participating centre
NHS Lothian
Waverley Gate
2-4 Waterloo Place
Edinburgh
United Kingdom
EH1 3EG

Study participating centre
NHS Forth Valley
33 Spittal Street
Stirling
United Kingdom
FK8 1DX

Sponsor information

Organisation
NHS Tayside

Sponsor details
TASC
Level 3
Ninewells Hospital and Medical School
Dundee
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United Kingdom
DD1 9SY
+44 (0)1382 383900
tascgovernance@dundee.ac.uk

Sponsor type
Hospital/treatment centre

Website
http://www.nhstayside.scot.nhs.uk/index.htm

ROR
https://ror.org/000ywep40

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

Funder Name
British Lung Foundation

Alternative Name(s)
BLF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan

Publication will include peer reviewed scientific journals, conference presentations, and dissemination to participants and public

Intention to publish date
30/09/2021

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version V1.1	03/09/2020	06/04/2021	No	No
HRA research summary			28/06/2023	No	No