ISRCTN44324934 https://doi.org/10.1186/ISRCTN44324934

The symptoms, virology and immunity of COVID in healthcare workers

Submission date
16/04/2020

Recruitment status
No longer recruiting

Registration date
18/05/2020

Overall study status
Completed

Last Edited
28/06/2024

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[X] 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.

Strategies to prevent spread of infection include social distancing and the development of a vaccine. These require detailed understanding of the disease. There are some basic questions about COVID-19 to which we urgently need answers, including:
1. How often are COVID-19 tests negative during the infection or positive without showing any signs of illness?
2. Can we reliably test for immunity to COVID-19 after infection or vaccination with a blood test?
3. How long after infection does immunity last?
To answer these questions, we need to understand the links between the symptoms of COVID-19, swab tests for infection and blood tests for immunity. The researchers will study all these things in doctors and nurses working in the Emergency Department of Bristol Royal Hospital for Children over a three month period starting in April 2020.

Who can participate?
Any patient-facing clinical staff member working regularly in the Children's Emergency Department (CED) of Bristol Royal Hospital for Children, including doctors, nurses and healthcare assistants.

What does the study involve?
Staff who agree to participate will fill out an online symptom dairy every day. Twice a week, participants will swab their own nose and throat and provide a saliva sample, which we can test for COVID-19 in the laboratory. Blood samples will be taken from participants at the beginning of the study, at 6-week intervals for 18 weeks, and again after a year. The main advantage of studying doctors and nurses is that they can easily and safely obtain samples from their own nose/throat/mouth. After the study has been completed, we will analyse the results and publish them in a scientific journal. This study will help us provide answers to the fundamental questions about COVID-19 infection that are needed to inform public health measures such as social distancing and vaccination.

What are the possible benefits and risks of participating?
Benefits - By taking part you will be contributing directly to understanding the relationship between symptoms, virology and immune responses to COVID-19. This will help improve public health measures to minimise transmission, and develop tests so that vaccines can be evaluated.
Risks - Taking a throat and nasal swab might be a bit uncomfortable for a few seconds. Blood tests can also be uncomfortable and cause mild bruising. All staff taking your blood are trained and experienced. Throughout the study you can contact the study team by phone or email if you have any questions or concerns.

Where is the study run from?
Bristol Royal Hospital for Children (UK)

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

Who is funding the study?
The Grand Appeal (UK)

Who is the main contact?
Unfortunately, this study is not recruiting public volunteers at this time. This is because the research isn't ready for volunteers yet or the researchers are directly identifying volunteers in certain areas or hospitals. Please do not contact the research team as they will not be able to respond. For more information about COVID-19 research, visit the Be Part of Research homepage.

Contact information

Type(s)
Scientific

Contact name
Prof Adam Finn

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Additional identifiers

Integrated Research Application System (IRAS)
282718

Study information

Scientific Title
Longitudinal study of COVID-19: symptoms, virology & immunity

Acronym
LOGIC

Study objectives
What are the dynamic relationships between symptoms, mucosal viral load and immunological responses, which are potential correlates of protection, in SARS-CoV-2 infection?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/04/2020, Yorkshire & The Humber - Leeds West Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)207 1048 088), ref: 20/YH/0148

Primary study design
Observational

Study design
Longitudinal observational cohort study

Study type(s)
Other

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

Interventions

1. Online consent, baseline data collection
2. Online daily symptom diary - for 3 months
3. Self-sampling upper respiratory tract (nose, throat & saliva) - twice weekly for 3 months
4. Blood sampling - weeks 0, 6, 12, 18 and 52

Intervention Type
Mixed

Primary outcome(s)
COVID-19 symptoms measured using online daily symptom diary every day for 3 months

Key secondary outcome(s)
1. COVID-19 infection measured using self-sampling of upper respiratory tract (nose, throat & saliva) - twice weekly for 3 months
2. Serum antibody levels and peripheral antigen-specific memory T cells measured using blood sampling at weeks 0, 6, 12, 18, and 52

Completion date
31/12/2021

Eligibility

Key inclusion criteria
Any patient-facing clinical staff member working regularly in the Children's Emergency Department (CED) of Bristol Royal Hospital for Children, including doctors, nurses and healthcare assistants

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
79

Key exclusion criteria
1. Staff who, on average, work less than two shifts per week
2. Staff who anticipate that they will not able to complete at least 6 weeks of the study, excluding annual leave e.g. about to go on maternity leave

Date of first enrolment
30/04/2020

Date of final enrolment
20/04/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Bristol Royal Hosptial for Children
University Hospitals Bristol and Weston NHS Foundation Trust
Upper Mauldin Street
Bristol
United Kingdom
BS2 8BJ

Sponsor information

Organisation
University of Bristol

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Charity

Funder Name
The Grand Appeal

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository.
Available indefinitely

Consent was obtained from participants to share these laboratory data
Data fully anonymised
No ethical or legal restrictions

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		09/11/2022	28/06/2024	Yes	No
Dataset			28/06/2024	No	No
HRA research summary			28/06/2023	No	No
Protocol file	version v1.1	19/04/2020	19/05/2020	No	No