

The symptoms, virology and immunity of COVID in healthcare workers

| | | |
|--|--|---|
| Submission date 16/04/2020 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 18/05/2020 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 28/06/2024 | Condition category Infections and Infestations | <input checked="" type="checkbox"/> 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 diary 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

ORCID ID

<http://orcid.org/0000-0003-1756-5668>

Contact details

Bristol Children's Vaccine Centre
Level 6 Education Centre
University Hospitals Bristol and Weston NHS Foundation Trust
Upper Mauldin Street
Bristol
United Kingdom
BS2 8AE
+44 (0)117 342 0172
adam.finn@bristol.ac.uk

Additional identifiers**EudraCT/CTIS number**

Nil known

IRAS number

282718

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Study design

Longitudinal observational cohort 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 contact details to request a participant information sheet.

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 measure

COVID-19 symptoms measured using online daily symptom diary every day for 3 months

Secondary outcome measures

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

Overall study start date

23/03/2020

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

Age group

Adult

Sex

Both

Target number of participants

135

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 be 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

England

United Kingdom

Study participating centre

Bristol Royal Hospital for Children

University Hospitals Bristol and Weston NHS Foundation Trust

Upper Mauldin Street

Bristol

United Kingdom

BS2 8BJ

Sponsor information

Organisation

University of Bristol

Sponsor details

Research Governance Team
Research & Enterprise Division
University of Bristol
Trinity Street, College Green
One Cathedral Square
Bristol
England
United Kingdom
BS1 5DD
+44 (0)117 394 0177
research-governance@bristol.ac.uk

Sponsor type

University/education

Website

<http://bristol.ac.uk/>

ROR

<https://ror.org/0524sp257>

Funder(s)**Funder type**

Charity

Funder Name

The Grand Appeal

Results and Publications**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

30/04/2022

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publicly 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? |
|--------------------------------------|--------------|--------------|------------|----------------|-----------------|
| Protocol file | version v1.1 | 19/04/2020 | 19/05/2020 | No | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Dataset | | 09/11/2022 | 28/06/2024 | No | No |
| Results article | | | 28/06/2024 | Yes | No |