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Coronavirus (COVID-19) antibody response in healthcare staff: What proportion of healthcare staff have COVID-19 antibodies? How long do the antibodies last? Do the antibodies protect against recurring infection?

Submission date
11/08/2020

Recruitment status
No longer recruiting

Registration date
13/08/2020

Overall study status
Completed

Last Edited
28/01/2022

Condition category
Respiratory

[ ] Prospectively registered
[ ] 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.

Antibodies detected by blood tests indicate that a person has been exposed to SARS-CoV-2 and developed antibodies as part of an immune response to the virus. Antibody tests are important to confirm prior infection, including in individuals with few or no symptoms. There are several different classes (or types) of antibody which may develop in response to any infection. These include immunoglobulin G (known as IgG) and immunoglobulin M (known as IgM).

This study will measure antibodies to COVID-19 in up to 2000 healthcare workers at Barts Health NHS Trust. The percentage of healthcare workers who have been exposed to the SARS-CoV-2 virus and who have developed antibodies will be reported. A proportion of the study participants will be called back for study visits at 3 months and at 6 months after enrolment. The aim of the follow-up visits is to measure how long the antibodies last, and also to determine if having antibodies to COVID-19 protects against getting COVID-19 disease a second time.

In the study, the COVID-19 antibodies will be measured using the Panbio™ COVID-19 IgG/IgM Rapid Test. The Panbio™ COVID-19 IgG/IgM Rapid Test is a test that uses a small drop of blood to detect IgG and IgM antibodies to SARS-CoV-2. Different types of human fluid samples including blood taken from a vein (venous whole blood), blood from a fingerstick (capillary whole blood) and serum or plasma (which are fluids prepared in a lab by processing whole blood samples) can be used on the Panbio™ COVID-19 IgG/IgM Rapid Test The test is interpreted 10-20 minutes after sample application. The result is qualitative, meaning it shows that the antibodies are, or are not, present, rather than giving a value or number to measure the antibodies. In the study, a positive test result will be confirmed by laboratory testing of the same blood sample using the Abbott Architect or Roche Elecsys SARS-CoV-2 antibody tests.

Who can participate?
Healthcare workers at Barts Health NHS Trust can participate in the study. This includes frontline staff such as doctors and nurses as well as administrative staff and other non-clinical staff.

What does the study involve?
During the initial study visit and follow-up visits, the study participants will be asked for a brief medical history, focussed on COVID-19 risk factors, past COVID-19 symptoms and COVID-19 testing. One tube of venous blood will be taken from each participant at each visit. Study participants are also asked to notify the study team of any potential COVID-19 symptoms that occur between visits by sending a message to a secure email address.

What are the possible benefits and risks of participating?
The study participants will receive their COVID-19 antibody result. It is possible that the collection of blood could cause discomfort. However, as this is a routine medical procedure and the samples will be obtained by trained medical personnel, the discomfort is likely to be minimized. COVID-19 transmission is a risk to the participants. However, convalescent patients are not expected to be transmitting the virus. Symptomatic participants, or participants with COVID-19 symptoms during the last 14 days are excluded from the study. All operations will be conducted under strict social distancing to minimize the risk of transmission.

Where is the study run from?
The study is run from Barts Health NHS Trust (UK) and is recruiting participants at 3-4 hospitals

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

Who is funding the study?
Abbott Rapid Diagnostics (Germany)

Who is the main contact?
Prof. Patrick T. Kennedy
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Contact information

Type(s)
Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
284671

Central Portfolio Management System (CPMS)
46155

Protocol serial number
CLDG-0504

Study information

Scientific Title
COVID-19 antibody response in healthcare staff: Prevalence, duration and protection against recurring infection

Acronym
COVID-19 Healthcare Worker Study

Study objectives
1. To assess the prevalence of past immune response to the SARS-CoV-2 virus among Healthcare Workers using measurements of SARS-CoV-2 antibodies
2. To evaluate the duration of SARS-CoV-2 antibodies at 3- and 6-months follow-up
3. To determine the incidence reduction of SARS-CoV-2 infection during the follow-up time

period in the population with a positive SARS-CoV-2 antibody result at enrolment, compared to the population with a negative SARS-CoV-2 antibody result at enrolment

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/05/2020, London - Camden & Kings Cross Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ; +44 (0)207 104 8086; CamdenandKingsCross.REC@hra.nhs.uk), ref 20/HRA/2675

Study design
Single-centre observational longitudinal cohort study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection) antibody response in healthcare workers

Interventions
This is an observational study. Participants will receive standard of care treatment for any conditions that arise during the study period. During the initial study visit and follow-up visits, the study participants will be asked for a brief medical history, focused on COVID-19 risk factors, past COVID-19 symptoms and COVID-19 testing. One tube of venous blood will be taken from each participant at each visit for antibody testing. Study participants are also asked to notify the study team of any potential COVID-19 symptoms that occur between visits by sending a message to a secure email address. Each study visit will last 15-30 minutes. Selected participants will be followed-up 3 months and 6 months after the enrollment study visit. The maximum duration of observation and follow up is 7 months from the date of enrollment.

Intervention Type
Other

Primary outcome(s)
Prevalence of past immune response to the SARS-CoV-2 virus among healthcare workers, as determined using measurements of SARS-CoV-2 antibodies from blood samples using the Panbio™ COVID-19 IgG/IgM Rapid Test, with confirmation of positive results using the Abbott Architect® SARS-CoV-2 IgG test, at baseline

Key secondary outcome(s))
1. Duration of SARS-CoV-2 antibodies at follow-up visits in those with a positive antibody test result at enrolment using measurements of SARS-CoV-2 antibodies from blood samples using the Panbio™ COVID-19 IgG/IgM Rapid Test, with confirmation of positive results using the Abbott Architect® SARS-CoV-2 IgG test, at baseline, 3 and 6 months
2. Incidence reduction of SARS-CoV-2 infection during the follow-up time period in the population with a positive SARS-CoV-2 antibody result at enrolment in comparison with a population with a negative SARS-CoV-2 antibody result at enrolment using measurements of

SARS-CoV-2 antibodies from blood samples using the Panbio™ COVID-19 IgG/IgM Rapid Test, with confirmation of positive results using the Abbott Architect® SARS-CoV-2 IgG test, at baseline, 3 and 6 months

Completion date
31/03/2021

Eligibility

Key inclusion criteria
1. Aged ≥18 years
2. Agrees to complete all aspects of the study

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Previously participated in this study on a previous occasion
2. Unable or unwilling to provide informed consent
3. Is a vulnerable person as deemed unfit for the study by the Principal Investigator
4. Current symptoms of COVID-19 or has had COVID-19 symptoms within the last 14 days

Date of first enrolment
02/06/2020

Date of final enrolment
21/08/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Barts Health NHS Trust
Whitechapel Rd
London
E1 1BB
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Sponsor information

Organisation
Abbott (Germany)

ROR
https://ror.org/02x2gk324

Funder(s)

Funder type
Industry

Funder Name
Abbott Rapid Diagnostics Jena GmbH

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available. This is due to the study being observational only, and consent has not been obtained for making de-identified participant data available under GDPR. The data will be clearly explained in a peer-reviewed publication.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	3-month follow-up results	27/04/2021	28/01/2022	Yes	No
HRA research summary			28/06/2023	No	No