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Analysis of the immunological response to coronavirus infection

Submission date	Recruitment status	[_] Prospectively registered
05/10/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/11/2020	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
05/11/2020	Infections and Infestations	[_] 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.
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 April 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.
The pandemic caused by SARS-CoV-2 has already led to over 1 million deaths worldwide. There is an urgent need to understand more about the biology of this disease. The aim of this study is to collect specimens from patients who have been confirmed to have active or convalescent (recovering from) SARS-CoV-2 infection, and a corresponding healthy control group, to assess the immunological response to the infection in patients with a range of clinical manifestations (symptoms) of the disease.

Who can participate?
Patients and members of the public who have been infected with SARS-CoV-2, whether or not they developed COVID-19 symptoms, and uninfected volunteers

What does the study involve?
The study involves donating blood samples, nasal swabs and/or samples of saliva. The volume and frequency of sampling depends on the specific sub-study a participant is involved in.

What are the possible benefits and risks of participating?
A number of participants are recruited at the time of donating a routine clinical sample, in which case the study doesn't present any additional risks. For those who donate a blood sample purely for research purposes the process carries the potential risk of a small bruise or mild soreness at the puncture site and the very rare possibility of infection at the puncture site.

Where is the study run from?
University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
April 2020 to June 2025

Who is funding the study?
1. Medical Research Council (UK)
2. Department of Health and Social Care (UK)

Who is the main contact?
Unfortunately, this study is not recruiting public volunteers at this time. This is because 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
282164

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 46588, IRAS 282164, RG_20-038 COVID-19

Study information

Scientific Title
Coronavirus Immunological Analysis (CIA)

Study objectives
The aim of this study is to collect specimens from patients who have been confirmed to have active or convalescent SARS-CoV-2 infection, and a corresponding healthy control group, to assess the immunological response to the infection in patients with a range of clinical manifestations of the disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/05/2020, North West - Preston Research Ethics Committee (Barlow House 3rd Floor 4 Minshull Street Manchester, M1 3DZ, UK; +44 (0)207 104 8056; preston.rec@hra.nhs.uk), REC ref: 20/NW/0240

Study design
Observational; Design type: Clinical Laboratory Study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
No participant information sheet available

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

Interventions
The researchers are taking blood samples by the process of phlebotomy and taking nasal swabs using the usual nasal swab kits and saliva collection using commercially available basic saliva collection kits.

Collection 1. 'Waste' samples from hospital diagnostic laboratories
Here the researchers will:
1. Identify patients who have been tested for SARS-CoV-2 infection status
2. Localise matched samples that are >24 hours old and on which all diagnostic tests have been performed
3. These samples will be used for immediate analysis or storage for later investigations
4. Samples will be taken daily on the identified patient so that a 'prospective' analysis can be undertaken

Collection 2. Samples from patients, and controls, in hospital under appropriate consent
Here the researchers will:
1. Identify patients who have been tested for SARS-CoV-2 infection and are in hospital
2. The managing clinical team will assess if the patient is well enough to consider consent and will then approach the patient
3. The patient will be offered a Patient Information Sheet
4. Consent and sample collection may then commence

Collection 3. Samples from patients, and controls, who are at home
Here the researchers will:
1. Identify patients who have been tested for SARS-CoV-2 infection and are not in hospital
2. Send a letter to the patient asking them to contact us if they are interested in giving samples
3. Send a Patient Information Sheet to responders
4. Consent and sample collection may occur in hospital or the community

Collection 4. Samples from healthy donors
Here the researchers will:
1. Invite volunteers to take part in the study
2. Give a Patient Information Sheet to responders
3. Consent and sample collection will occur in University or hospital facility

Intervention Type
Other

Primary outcome measure
1. Presence of immune response to SARS-CoV-2 measured using enzyme-linked immunosorbent assay (ELISA) and direct solid-state protein-binding assays such as Meso Scale Discovery (MSD) at various timepoints depending on the patient

2. Immunological and biological response to SARS-CoV-2 infection and its correlation with clinical outcome, measured using flow cytometry, proteomic analyses and functional studies at various timepoints depending on the patient

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/04/2020

Completion date
05/06/2025

Eligibility

Key inclusion criteria
Patients and volunteers who have been tested for SARS-CoV-2 infection (both positive and negative for infection) and a matched control group

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 600; UK Sample Size: 600

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
15/05/2020

Date of final enrolment
05/05/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Queen Elizabeth Hospital Birmingham
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2GW

Study participating centre
Heartlands Hospital Bordesley Green East
Bordesley Green
Birmingham
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B9 5SS

Study participating centre
Good Hope Hospital
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B75 7RR

Sponsor information

Organisation
University of Birmingham

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Sponsor type
University/education

Funder(s)

Funder type

Government

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Department of Health and Social Care (UK)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal within 24 months of recruitment start.

Intention to publish date
15/05/2022

Individual participant data (IPD) sharing plan
The raw datasets will not be available, but the analysed data will be made available in peer-reviewed journals.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No