

Analysis of the immunological response to coronavirus infection

Submission date 05/10/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 05/11/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 05/11/2020	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Contact name

Prof Paul Moss

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
282164

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)

Diagnostic

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(s)

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

Key secondary outcome(s)

There are no secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

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

United Kingdom
B9 5SS

Study participating centre

Good Hope Hospital

Rectory Road
Sutton Coldfield
United Kingdom
B75 7RR

Sponsor information

Organisation

University of Birmingham

Funder(s)

Funder type

Government

Funder Name

Medical Research Council

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory 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

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