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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 | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 02/06/2026 | Infections and Infestations | |

**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

### ORCID ID
https://orcid.org/0000-0002-6895-1967

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# Additional identifiers

### Integrated Research Application System (IRAS)
282164

### Central Portfolio Management System (CPMS)
46588

### Protocol serial number
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

### Primary study design
Observational

### Study design
Observational; Design type: Clinical Laboratory Study

### 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

**Total final enrolment**
0

**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
England
B15 2GW

**Study participating centre**
**Heartlands Hospital Bordesley Green East**
Bordesley Green
Birmingham

England
B9 5SS

**Study participating centre**
**Good Hope Hospital**
Rectory Road
Sutton Coldfield
England
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

### 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 | Age impact; samples used as a validation cohort | 25/06/2024 | 02/06/2026 | Yes | No |
| Results article | Nasal mucosal IgA levels in children; samples used as the healthy adult comparison cohort | 03/09/2023 | 02/06/2026 | Yes | No |
| Results article | spike-specific immune responses up to 8 months following 3 different COVID-19 vaccine regimens in older people | 25/08/2022 | 02/06/2026 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |