COVID-19: Healthcare Worker Bioresource: Immune Protection and Pathogenesis in SARS-CoV-2 (COVID19-HCW)

ClinicalTrials.gov Identifier: NCT04318314

Recruitment Status : Recruiting
First Posted : March 23, 2020
Last Update Posted : May 21, 2020

See Contacts and Locations

Sponsor:
University College, London

Collaborators:
St. Bartholomew's Hospital
Royal Free Hospital NHS Foundation Trust
UCLH

Information provided by (Responsible Party):
University College, London

Study Description

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Brief Summary:

Modelling repurposed from pandemic influenza is currently informing all strategies for SARS-CoV-2 and the disease COVID-19. A customized disease specific understanding will be important to understand subsequent disease waves, vaccine development and therapeutics. For this reason, ISARIC (the International Severe Acute Respiratory and Emerging Infection Consortium) was set up in advance. This focuses on hospitalised and convalescent serum samples to understand severe illness and associated immune response. However, many subjects are seroconverting with mild or even subclinical disease. Information is needed about subclinical infection, the significance of baseline immune status and the earliest immune changes that may occur in mild disease to compare with those of SARS-CoV-2. There is also a need to understand the vulnerability and response to COVID-19 of the NHS workforce of healthcare workers (HCWs). HCW present a cohort with likely higher exposure and seroconversion rates than the general population, but who can be followed up with potential for serial testing enabling an insight into early disease and markers of risk for disease severity. We have set up "COVID-19: Healthcare worker Bioresource: Immune Protection and Pathogenesis in SARS-CoV-2". This urgent fieldwork aims to secure significant (n=400) sampling of healthcare workers (demographics, swabs, blood sampling) at baseline, and weekly whilst they are well and attending work, with acute sampling (if hospitalised, via ISARIC, if their admission hospital is part of the ISARIC network) and convalescent samples post illness. These will be used to address specific questions around the impact of baseline immune function, the earliest immune responses to infection, and the biology of those who get non-hospitalized disease for local research and as a national resource. The proposal links directly with other ongoing ISARIC and community COVID projects sampling in children and the older age population. Reasonable estimates suggest the usable window for baseline sampling of NHS HCW is closing fast (e.g. baseline sampling within 3 weeks).

Condition or disease	Intervention/treatment
Health Care Worker Patient Transmission	Diagnostic Test: COPAN swabbing and blood sample collection
Coronavirus	
Coronavirus Infections	
Immunological Abnormality	

Detailed Description:

The proposed study is a prospective observational cohort design which will be carried out across three different trusts: Barts Health NHS Trust (St Bartholomew's Hospital, The Royal London Hospital, Whipps Cross Hospital and Newham Hospital), Royal Free London NHS Foundation Trust (Royal Free Hospital) and University College London Hospitals NHS Foundation Trust (UCLH).

Participants will be asymptomatic front-facing HCWs who carry out their tasks in different areas of the corresponding hospital: Accident and Emergency, Adult Medical Admissions Unit, Medical and Surgical Wards and Intensive Care Units.

This study substantially uses existing infrastructure: Recruits into this study who are subsequently suspected to have COVID-19 can be co-recruited into ISARIC using ISARIC Ethics Ref: 13/SC/0149 (Oxford C Research Ethics Committee, UK CRN /CPMS ID 14152 IRAS ID126600 for acute samples and data collection. Sampling can be delivered via existing research personnel from furloughed projects (CLRN nurses, research fellows, Barts Bioresource). Convalescent sampling will be via an otherwise inactive Clinical Trials unit. It

Study Design

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Study Type :	Observational [Patient Registry]
Estimated Enrollment :	400 participants
Observational Model:	Cohort
Time Perspective:	Prospective
Target Follow-Up Duration:	6 Months
Official Title:	COVID-19: Healthcare Worker Bioresource: Immune Protection and Pathogenesis in SARS-CoV-2
Actual Study Start Date :	March 18, 2020
Estimated Primary Completion Date :	December 31, 2020
Estimated Study Completion Date :	December 31, 2021

Resource links provided by the National Library of Medicine NLM

MedlinePlus related topics: Health Facilities

Genetic and Rare Diseases Information Center resources: Severe Acute Respiratory Syndrome

U.S. FDA Resources

Groups and Cohorts

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Group/Cohort	Intervention/treatment
Healthy and asymptomatic healthcare workers Healthy and asymptomatic healthcare workers	Diagnostic Test: COPAN swabbing and blood sample collection COPAN swabbing of nostrils and/or oropharynx and blood sample collection

Outcome Measures

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Primary Outcome Measures :

1. Seroconversion to SARS-CoV-2 positivity [Time Frame: Within 6 months]

   Home-isolation or hospital admission

Biospecimen Retention: Samples With DNA
Blood samples Nasal and oropharygeal swabs

Eligibility Criteria

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Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Sampling Method:	Non-Probability Sample

Study Population

Healthy asymptomatic healthcare workers attending their usual place of work that can be St Bartholomew's Hospital, Royal Free London or UCLH.

Criteria

Inclusion Criteria:

- healthy asymptomatic healthcare workers attending hospital (place of work)

Exclusion Criteria:

- SARS-CoV-2 positive or symptomatic healthcare workers

Contacts and Locations

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Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04318314***

Contacts

Contact: James C Moon, MD MBBS MRCP 07570911438 bartshealth.covid-hcw@nhs.net

Contact: Mahdad Noursadeghi

Locations

United Kingdom

Barts Heart Center — **Recruiting**
London, United Kingdom
Contact: James Moon
Principal Investigator: James Moon

Royal Free London NHS Foundation Trust — **Active, not recruiting**
London, United Kingdom

Sponsors and Collaborators

University College, London

St. Bartholomew's Hospital

Royal Free Hospital NHS Foundation Trust

UCLH

Investigators

Principal Investigator:	James C Moon	BHC & UCL
Study Director:	Charlotte Manisty	BHC & UCL
Principal Investigator:	Thomas Treibel	Barts Heart Center

More Information

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Responsible Party:	University College, London
ClinicalTrials.gov Identifier:	NCT04318314 History of Changes
Other Study ID Numbers:	130852
First Posted:	March 23, 2020 Key Record Dates
Last Update Posted:	May 21, 2020
Last Verified:	May 2020

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:	Yes
Plan Description:	Publication of results in open access journals; sharing of results in scientific databases.
Supporting Materials:	Study Protocol Statistical Analysis Plan (SAP) Informed Consent Form (ICF)

Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No

Additional relevant MeSH terms:

- Coronavirus Infections
- Severe Acute Respiratory Syndrome
- Coronaviridae Infections
- Nidovirales Infections
- RNA Virus Infections
- Virus Diseases
- Respiratory Tract Infections
- Respiratory Tract Diseases

Transparency data

Innovate UK funded projects since 2004

Information about the projects funded by Innovate UK between 2004 and 1 February 2021.

From: Innovate UK and UK Research and Innovation
Published: 12 May 2014
Last updated: 11 February 2021, see all updates

Documents

Innovate UK funded projects 2004 to 1 February 2021

MS Excel Spreadsheet, 15.1MB

This file may not be suitable for users of assistive technology.

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Details

The spreadsheet includes data about all collaborative research and development (R&D), feasibility, smart and innovation voucher grants, and Knowledge Transfer Partnerships between 2004 and 1 February 2021. An explanation has been provided in the header tab of the report. The comment box has been used to explain briefly what the information is reporting.

Note: These proposals have succeeded in the assessment stage of this competition. All are subject to grant offer and conditions being met.

You can also see all publicly funded projects by Innovate UK and the research councils on the Gateway to Research database.

Published 12 May 2014
Last updated 11 February 2021 + show all updates

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Competition Reference	Competition Title	Programme Title	Sector	Application Number	Project Number
2003_CRD_CO_COVID19_P1	Business-led innovation in response to global disruption	Business-Led Innovation in Response to Global Disruption (De Minimis)	Responsive	00059274	59274

Project Title	Public Description	Competition Year
High-throughput saliva COVID-19 antibody test	The 2019-novel Corona virus (SARS-CoV2) can cause Severe Acute Respiratory Syndrome also called COVID-19. According to recent reports, most COVID-19 patients have mild flu like symptoms, however, a fraction of those infected rapidly progress to acute respiratory distress syndrome (ARDS), septic shock and further complications sometimes leading to death. The U.K. is one of the worst hit countries in terms of the death toll and the economic impact arising from Covid-19 infections and its control measures. The U.K. government like many other health authorities in the world have put in place drastic social distancing measures as their main strategy to avoid the spread of the disease. According to World Health Organization (W.H.O.), a combination of measures such as rapid diagnosis and immediate isolation of cases are needed to stop the spread of the virus. However, often even those with clinical symptoms aren't able to get a test due to the growing demand. Until a vaccine becomes available the only way to prevent the rapid spread of Covid-19 will be by mass testing, not only to detect those with active infections but also those who have recovered from the infection. The current testing approach relies on detection of the viral genetic material using RT-qPCR. These tests are generally quite reliable, however, they need samples obtained from unpleasant nasopharyngeal swabs. Swabs can often miss the virus as it could either be present in very low amounts in a patient (in cases of early infection or after recovery from infection) or it could just be present in a different area of the throat where the swab couldn't reach. This can lead to false-negative results. An alternative and reliable way of detecting Covid-19 is by measuring the antibodies produced by the individual in response to the infection. This detection can also work for those who have recovered from the infection. While such tests are often done using blood, Vidya's innovative technology can reliably and accurately detect antibodies against Covid-19 in samples other than blood. The tests requires the user to collect their sample (non-invasively) in a vial sent to them by post to be returned to Vidya's central testing lab also via post. Vidya's ultrasensitive, high-throughput technology can provide the user with their results within 24 hours of sample reception.	2020/21

Innovate UK Product Type	Participant Name	Is Lead Participant	CRN	Project Start Date	Project End Date	Grant Offered (£)
Feasibility Studies	VIDYA HOLDINGS LTD	Yes	11036007	01/06/2020	31/03/2021	67,169.22

Total Costs (£)	Actual Spend to Date (£)	Participant Withdrawn From Project	Project Status	Enterprise Size	Postcode	Address Region
71,785.00	46,785.00	Active	Live	Micro/Small	EC1N 8QQ	London

Address LEP	In Multiple LEPs	Industrial Strategy Challenge Fund (ISCF)
London	No	No