

Long-term follow up of adults hospitalised with COVID-19

Submission date 16/07/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/07/2020	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/01/2025	Condition category Infections and Infestations	<input type="checkbox"/> 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 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 COVID-19 pandemic has tragically led to severe acute illness, hospitalisation and death. Beyond the health of those affected, it has had widespread economic, psychological and societal effects. The clinical spectrum is broad, ranging from those with no or minimal symptoms to severe pneumonia in 15-20% with evidence of widespread disease beyond the lung. As we emerge from the first wave of the pandemic we have new insights into the acute phase of this disease but very little information concerning the long-term effects of COVID-19 and the ongoing medical, psychological and rehabilitation needs of these patients. This will be a national UK research study, embedded within clinical care, that aims to understand and improve long-term outcomes for survivors following hospitalisation with COVID-19. This study includes expert groups across the UK and will use standardised assessments of patients, including advanced imaging, recording of information and collection of samples. This study will provide researchers with a comprehensive understanding of the impact on the health of those that have been hospitalised with COVID-19. This will enable trials of new strategies of clinical care including personalised treatments to improve the long-term outcome of current and future COVID-19 survivors.

Who can participate?

Patients aged over 18 who were admitted to a UK hospital and discharged following suspected COVID-19

What does the study involve?

The researchers will collect data from any clinic visits and from routine health records of all participants. This will include signs and symptoms, medication, physical test results, questionnaire answers, laboratory test results and imaging. In a subset of participants, the researchers will undertake additional research tests and obtain samples (for example, blood) for research experiments. Some participants may be asked to take part in additional studies.

What are the possible benefits and risks of participating?

There is no direct benefit to participants as this study will not directly change the clinical care that they receive. The information that is collected may help clinicians to better care for other patients in the future. If there are any test results that require follow-up, the participants' doctor will be informed. The researchers will not share the results from unvalidated research tests using the samples (for example, genetic data). Some participants may be asked to provide additional samples in addition to those needed for their clinical care. Whenever possible these samples will be taken at the same time as regular samples to reduce the extra procedures and participants will be advised on the maximum amount of sample that we will take when they agree to take part (and they will be free to decline any extra tests or samples). There is a risk of pain or discomfort when samples are taken, and these are detailed in the participant information sheet.

Where is the study run from?

The study is led by the University of Leicester and participants will be recruited at multiple hospital sites from across the UK (including Scotland, Wales and Northern Ireland)

When is the study starting and how long is it expected to run for?

April 2020 to December 2046

Who is funding the study?

This study is supported by a grant to the University of Leicester from the MRC-UK Research and Innovation, and National Institute for Health Research (NIHR) rapid response panel to tackle COVID-19 and by core funding provided by NIHR Leicester Biomedical Research Centre - a partnership between the University of Leicester and University Hospitals of Leicester NHS Trust.

Who is the main contact?

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phosp@leicester.ac.uk

Contact information

Type(s)

Scientific

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Groby Road
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LE3 9QP

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University of Leicester
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Public

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Department of Respiratory Sciences
College of Life Sciences
Glenfield Hospital
Groby Road
Leicester
United Kingdom
LE3 9QP

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phosp@leicester.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)

285439

Protocol serial number

CPMS 46443, IRAS 285439

Study information

Scientific Title

Post-hospitalisation COVID-19 study: a national consortium to understand and improve long-term health outcomes (PHOSP-COVID)

Acronym

PHOSP-COVID

Study objectives

The aims of this study are to:

1. Determine the short to long-term chronic health (and health economic) sequelae of COVID-19 infection in post-hospitalisation survivors; to define demographic, clinical and molecular biomarkers of the susceptibility, development, progression and resolution of these health sequelae
2. Understand the impact of interventions during the acute illness on these long-term sequelae
3. Build the foundation for multiple in-depth studies e.g. lung fibrosis, pulmonary and systemic vasculature, cardiometabolic, renal, sarcopenia, rehabilitation, mental health and neurological disease.

The findings will inform precision medicine in at-risk groups by directing new clinical trials and care for current and future post-COVID-19 patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 14/07/2020, Yorkshire & The Humber -Leeds West Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)207 972 2504, +44 (0)207 104 8088, +44 (0)207 104 8018; leedswest.rec@hra.nhs.uk), REC ref: 20/YH/0225

Study design

Prospective observational longitudinal study

Primary study design

Observational

Study type(s)

Other

Health condition(s) or problem(s) studied

Adult survivors of a hospital admission with COVID-19 (SARS-CoV-2 infection)

Interventions

PHOSP-COVID is an observational longitudinal follow-up study of adults post-hospitalisation with COVID-19. The researchers propose to analyse routine clinical data with linkage to retrospective and prospective health and social care records (Tier 1), enhanced clinical data and research-specific biosampling (Tier 2) and re-call of participants by genotype and phenotype for more detailed studies (Tier 3).

All participants will be followed up for at least 12 months after discharge from hospital. The researchers will ask participants for their agreement to continue to extract data from their electronic records, and to be contacted about future research, for at least 25 years after recruitment to the study.

Intervention Type

Other

Primary outcome(s)

Current primary outcome measure as of 18/11/2021:

1. Incidence of long-term sequelae of COVID-19 measured using multiple methods including:
 - 1.1. Symptoms and quality of life measured using one or more of the following questionnaires: EQ-5D, Dyspnoea-12, Fatigue (FACIT), Brief Pain Inventory (BPI), MRC dyspnoea score, Montreal Cognitive Assessment (MoCA), Clinical Frailty Scale
 - 1.2. Mental health: symptoms of anxiety assessed using Generalised Anxiety Disorder Assessment (GAD-7), depression assessed using Patient Health Questionnaire (PHQ-9), post-traumatic stress disorder (PTSD) checklist (PCL-5)
 - 1.3. Physical function measured using one or more the following tests: Short Physical Performance Battery (SPPB), Incremental Shuttle Walk Test (ISWT), muscle strength tests (handgrip strength), physical activity monitoring
 - 1.4. Biological samples taken e.g blood, urine, sputum, saliva, breath

1.5. Any imaging as part of clinical care

Measured at 6 weeks - 7.5 months and 12 months post-hospital discharge (and at regular timepoints thereafter for up to 25 years)

Please note that not all participants will be asked to complete or perform all of the above questionnaires and tests. Data from routine clinical investigations and tests will be recorded.

2. Healthcare utilisation measured using questionnaires and linkage to health and social care records at 6 weeks, 3 months, 6 months and 12 months post-hospital discharge (and at regular timepoints thereafter for up to 25 years)

3. Mortality measured using ONS data at 6 weeks, 3 months, 6 months and 12 months post-hospital discharge (and at regular timepoints thereafter for up to 25 years)

Previous primary outcome measure:

1. Incidence of long-term sequelae of COVID-19 measured using multiple methods including:

1.1. Symptoms and quality of life measured using one or more of the following questionnaires: EQ-5D, Sarcopenia screen (SARC-F), General Practice Physical Activity Questionnaire (GPPAQ), Dyspnoea-12, Fatigue (FACIT), Brief Pain Inventory (BPI), Nottingham extended activity of daily living (NEADL), MRC dyspnoea score, Montreal Cognitive Assessment (MoCA), Clinical Frailty Scale, Fried Frailty assessment

1.2. Mental health: symptoms of anxiety assessed using Generalised Anxiety Disorder Assessment (GAD-7), depression assessed using Patient Health Questionnaire (PHQ-9), post-traumatic stress disorder (PTSD) checklist (PCL-5)

1.3. Physical function measured using one or more the following tests: Short Physical Performance Battery (SPPB), Incremental Shuttle Walk Test (ISWT), muscle strength tests (handgrip and quadriceps strength), physical activity monitoring, cardiometabolic risk assessment and body composition measurements

1.4. Biological samples taken e.g blood, urine, sputum, saliva, breath

1.5. Any imaging as part of clinical care

Measured at 6 weeks, 3 months, 6 months and 12 months post-hospital discharge (and at regular timepoints thereafter for up to 25 years)

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3. Mortality measured using ONS data at 6 weeks, 3 months, 6 months and 12 months post-hospital discharge (and at regular timepoints thereafter for up to 25 years)

Key secondary outcome(s)

Current secondary outcome measures as of 18/11/2021:

Characterisation of specific long-term morbidities and impacts of COVID-19 hospitalisation measured using multiple methods including:

1. Symptoms and quality of life measured using one or more of the following questionnaires: EQ-5D, Sarcopenia screen (SARC-F), General Practice Physical Activity Questionnaire (GPPAQ), Dyspnoea-12, Fatigue (FACIT), Brief Pain Inventory (BPI), Nottingham extended activity of daily living (NEADL), MRC dyspnoea score, Montreal Cognitive Assessment (MoCA), Clinical Frailty Scale, Fried Frailty assessment

2. Mental health: symptoms of anxiety assessed using Generalised Anxiety Disorder Assessment (GAD-7), depression assessed using Patient Health Questionnaire (PHQ-9), post-traumatic stress

disorder (PTSD) checklist (PCL-5)

3. Physical function measured using one or more the following tests: Short Physical Performance Battery (SPPB), Incremental Shuttle Walk Test (ISWT), muscle strength tests (handgrip and quadriceps strength), physical activity monitoring, cardiometabolic risk assessment and body composition measurements

4. Biological samples taken e.g blood, urine, sputum, saliva, breath

5. Any imaging as part of clinical care

6. Healthcare utilisation assessed from linkage to health and social care records

Measured at 6 weeks - 7.5 months and 12 months post-hospital discharge (and at regular timepoints thereafter for up to 25 years)

Please note that not all participants will be asked to complete or perform all of the above questionnaires and tests. Data from routine clinical investigations and tests will be recorded.

Previous secondary outcome measures:

Characterisation of specific long-term morbidities and impacts of COVID-19 hospitalisation measured using multiple methods including:

1. Symptoms and quality of life measured using one or more of the following questionnaires: EQ-5D, Sarcopenia screen (SARC-F), General Practice Physical Activity Questionnaire (GPPAQ), Dyspnoea-12, Fatigue (FACIT), Brief Pain Inventory (BPI), Nottingham extended activity of daily living (NEADL), MRC dyspnoea score, Montreal Cognitive Assessment (MoCA), Clinical Frailty Scale, Fried Frailty assessment

2. Mental health: symptoms of anxiety assessed using Generalised Anxiety Disorder Assessment (GAD-7), depression assessed using Patient Health Questionnaire (PHQ-9), post-traumatic stress disorder (PTSD) checklist (PCL-5)

3. Physical function measured using one or more the following tests: Short Physical Performance Battery (SPPB), Incremental Shuttle Walk Test (ISWT), muscle strength tests (handgrip and quadriceps strength), physical activity monitoring, cardiometabolic risk assessment and body composition measurements

4. Biological samples taken e.g blood, urine, sputum, saliva, breath

5. Any imaging as part of clinical care

6. Healthcare utilisation assessed from linkage to health and social care records

Measured at 6 weeks, 3 months, 6 months and 12 months post-hospital discharge (and at regular timepoints thereafter for up to 25 years)

Please note that not all participants will be asked to complete or perform all of the above questionnaires and tests. Data from routine clinical investigations and tests will be recorded.

Completion date

31/12/2046

Eligibility

Key inclusion criteria

1. Participant admitted to an acute admissions unit or ward at a UK hospital and discharged with suspected COVID-19

2. Age 18 years and over
3. Participant is willing and able to give informed consent for participation in the study
4. Aged 18 years or above

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Confirmed diagnosis of a pathogen unrelated to the objectives of this study and no indication or likelihood of co-infection with a relevant pathogen
2. Attendance at an A&E or emergency department only
3. Refusal by participant, parent or appropriate representative
4. Other life-limiting illness with life expectancy <6 months such as disseminated malignancy

Date of first enrolment

25/07/2020

Date of final enrolment

01/03/2022

Locations**Countries of recruitment**

United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre

Queen Elizabeth Hospital

Heritage Building

University Hospitals of Birmingham NHS Trust

Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2TH

Study participating centre

Hull Royal Infirmary

Hull University Teaching Hospitals NHS Trust
Anlaby Rd
Hull
United Kingdom
HU3 2JZ

Study participating centre

Bradford Royal Infirmary

Bradford Teaching Hospitals NHS Foundation Trust
Duckworth Ln
Bradford
United Kingdom
BD9 6RJ

Study participating centre

Southmead Hospital

North Bristol NHS Trust
Southmead Rd
Bristol
United Kingdom
BS10 5NB

Study participating centre

Fulbourn Hospital

Cambridgeshire and Peterborough NHS Foundation Trust
Elizabeth House
Cambridge
United Kingdom
CB21 5EF

Study participating centre

Royal Papworth Hospital

Royal Papworth Hospital NHS Foundation Trust

Papworth Rd
Trumpington
Cambridge
United Kingdom
CB2 0AY

Study participating centre

Leeds General Infirmary

The Leeds Teaching Hospitals NHS Trust
Great George St
Leeds
United Kingdom
LS1 3EX

Study participating centre

Glenfield Hospital

University Hospitals of Leicester NHS Trust
Groby Road
Leicester
United Kingdom
LE3 9QP

Study participating centre

Royal Liverpool Hospital

Liverpool University Hospitals NHS Foundation Trust
Prescot St
Liverpool
United Kingdom
L7 8XP

Study participating centre

St Mary's Hospital

Imperial College Healthcare NHS Trust
The Bays
South Wharf Road
London
United Kingdom
W2 1NY

Study participating centre

Chelsea & Westminster Hospital

Chelsea & Westminster Hospital NHS Trust
369 Fulham Rd
Chelsea
London
United Kingdom
SW10 9NH

Study participating centre**Northwick Park Hospital**

London North West University Healthcare NHS Trust
Central Middlesex
Ealing Hospital
London
United Kingdom
HA1 3UJ

Study participating centre**Mount Vernon Hospital**

The Hillingdon Hospitals NHS Foundation Trust
Rickmansworth Road
Northwood
London
United Kingdom
HA6 2RN

Study participating centre**Royal Brompton & Harefield Trust**

Royal Brompton Hospital
1 Manresa Rd
Chelsea
London
United Kingdom
SW3 6LR

Study participating centre**St Thomas' Hospital**

Guy's and St Thomas' NHS Foundation Trust
Westminster Bridge Rd
London
United Kingdom
SE1 7EH

Study participating centre

King's College Hospital

King's College Hospital NHS Foundation Trust
Denmark Hill
Brixton
London
United Kingdom
SE5 9RS

Study participating centre

The Royal Hospital

Barts Health NHS Trust
Whitechapel Rd
London
United Kingdom
E1 1BB

Study participating centre

University College London Hospital

University College London Hospitals NHS Foundation Trust
235 Euston Road
Bloomsbury
London
United Kingdom
NW1 2BU

Study participating centre

The Whittington Hospital

Whittington Health NHS Trust
Magdala Ave
London
United Kingdom
N19 5NF

Study participating centre

Royal Free Hospital

Royal Free London NHS Foundation Trust
17 Lyndhurst Gardens
Hampstead

London
United Kingdom
NW3 5NU

Study participating centre

North Middlesex University Hospital
North Middlesex University Hospital NHS Trust
Sterling Way
London
United Kingdom
N18 1QX

Study participating centre

St George's Hospital
St George's University Hospitals NHS Foundation Trust
Blackshaw Road
Tooting
London
United Kingdom
SW17 0QT

Study participating centre

Manchester Royal Infirmary
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre

Salford Royal Hospital
Salford Royal NHS Foundation Trust
Stott Ln
Salford
United Kingdom
M6 8HD

Study participating centre

Freeman Hospital
Newcastle Upon Tyne Hospitals NHS Foundation Trust

Freeman Road
High Heaton
Newcastle-upon-Tyne
United Kingdom
NE7 7DN

Study participating centre

Belfast City Hospital

Belfast Health and Social Care Trust
A Floor
Lisburn Road
Belfast
United Kingdom
BT9 7AB

Study participating centre

Nottingham City Hospital

Nottingham University Hospitals NHS Trust
Hucknall Road
Nottingham
United Kingdom
NG5 1PB

Study participating centre

John Radcliffe Hospital

Oxford University Hospitals NHS Foundation Trust
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre

NHS Grampian

Summerfield House
2 Eday Road
Aberdeen
United Kingdom
AB15 6RE

Study participating centre

NHS Dumfries and Galloway

21-22 High St
Moffat
United Kingdom
DG10 9HL

Study participating centre

NHS Tayside

230 Clepington Rd
Dundee
United Kingdom
DD2 1GZ

Study participating centre

NHS Fife

Hayfield House
Hayfield Rd
Kirkcaldy
United Kingdom
KY2 5AH

Study participating centre

NHS Forth Valley

Stirling Rd
Larbert
United Kingdom
FK5 4WR

Study participating centre

NHS Highland

Inverness Retail and Business Park
John Dewar Building
Highlander Way
Inverness
United Kingdom
IV2 7GE

Study participating centre

NHS Greater Glasgow and Clyde

1055 Great Western Road
Glasgow

United Kingdom
G12 0XH

Study participating centre

NHS Lothian

Search Results
Morningside Pl
Edinburgh
United Kingdom
EH10 5HF

Study participating centre

Royal Hallamshire Hospital

Sheffield Teaching Hospitals NHS Foundation Trust
Glossop Rd
Broomhall
Sheffield
United Kingdom
S10 2JF

Study participating centre

Southampton General Hospital,

University Hospital Southampton NHS Foundation Trust
Tremona Rd
Southampton
United Kingdom
SO16 6YD

Study participating centre

Hywel Dda University Health Board

Ystwyth Building
St Davids Park
Jobswell Road
Carmarthen
United Kingdom
SA31 3BB

Study participating centre

Swansea Bay University Health Board

1 Talbot Gateway
Baglan Energy Park

Baglan
Port Talbot
United Kingdom
SA12 7BR

Study participating centre
Cardiff & Vale University Health Board
Heath Park
Cardiff
United Kingdom
CF14 4XW

Study participating centre
Aneurin Bevan University Health Board
Ringland Circle
Newport
United Kingdom
NP19 9PS

Study participating centre
Betsi Cadwaladr University Health Board
Glan Clwyd Hospital
Sarn Ln
Bodelwyddan
Rhyl
United Kingdom
LL18 5UJ

Study participating centre
Lanarkshire Primary Care NHS Trust
East Kilbride
Glasgow
United Kingdom
G75 8NH

Sponsor information

Organisation
University of Leicester

ROR

<https://ror.org/04h699437>

Funder(s)

Funder type

Government

Funder Name

UK Research and Innovation

Alternative Name(s)

UKRI

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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

National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Funder Name

University of Leicester

Alternative Name(s)

UniofLeicester, UoL

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

Funder Name

University Hospitals of Leicester NHS Trust

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Participant-level data will be made available for bona fide researchers via application. Researchers interested in accessing the data should contact phosp@leicester.ac.uk or visit <http://www.phosp.org> for more details of the process and an application form. Access to data and materials and the study are reviewed and approved by an independent data and materials access committee. Participants have provided appropriate consent to share their anonymised (pseudonymised) data. All access to data will be subject to agreement to appropriate terms and conditions.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		07/10/2021	11/10/2021	Yes	No
Results article	clinical characteristics with inflammation profiling of Long-COVID and association with one-year recovery following hospitalisation in the UK	22/04/2022	27/04/2022	Yes	No
Results article	prevalence of physical frailty, including risk factors, up to 1 year after hospitalisation for COVID-19 in the UK	11/03/2023	21/03/2023	Yes	No
Results article	Association of blood biomarkers with cognitive deficits	31/08/2023	28/09/2023	Yes	No
Results article	Long COVID and cardiovascular disease	27/05/2024	28/05/2024	Yes	No
Results article	Long term health outcomes in people with diabetes	27/12/2024	27/01/2025	Yes	No
HRA research summary			26/07/2023	No	No
Interim results article	Two doses of SARS-CoV-2 vaccination induce robust immune responses to emerging SARS-CoV-2 variants of concern	17/08/2021	19/08/2021	Yes	No
Interim results article	Symptom Persistence Despite Improvement in Cardiopulmonary Health - Insights from longitudinal CMR, CPET and lung function testing post-COVID-19	20/10/2021	26/10/2021	Yes	No
Preprint results	preprint of clinical characteristics with inflammation profiling of Long-COVID and association with one-year recovery following hospitalisation in the UK	15/12/2021	16/12/2021	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes