ISRCTN10980107 https://doi.org/10.1186/ISRCTN10980107

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

Submission date
16/07/2020

Recruitment status
No longer recruiting

Registration date
22/07/2020

Overall study status
Ongoing

Last Edited
27/01/2025

Condition category
Infections and Infestations

[X] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[X] Results

[_] 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 byNIHR Leicester Biomedical Research Centre - a partnership between the University of Leicester and University Hospitals of Leicester NHS Trust.

Who is the main contact?
Prof. Chris Brightling
phosp@leicester.ac.uk

Study website
https://www.phosp.org/

Contact information

Type(s)
Scientific

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United Kingdom
LE3 9QP
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phosp@leicester.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number
285439

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

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 measure
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)
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)

Secondary outcome measures

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.

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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.

Overall study start date
15/04/2020

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
10000

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
England

Northern Ireland

Scotland

United Kingdom

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

Sponsor details
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Leicester
England
United Kingdom
LE1 7RH
+44 (0)116 252 2522
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Sponsor type
University/education

Website
https://le.ac.uk/about

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, 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)
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

Publication and dissemination plan
Results of the study will be made available in a timely fashion and published in a high-impact peer-reviewed journal.

Intention to publish date
31/01/2022

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?

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
Results article		07/10/2021	11/10/2021	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
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
HRA research summary			26/07/2023	No	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