ISRCTN58667920 https://doi.org/10.1186/ISRCTN58667920

COVID-19 effects on the heart

Submission date
03/08/2020

Recruitment status
No longer recruiting

Registration date
04/08/2020

Overall study status
Completed

Last Edited
02/09/2024

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Up to 1 in 5 patients hospitalised by COVID-19 have evidence of heart muscle injury as measured from a blood test. This is associated with a high death rate. Using an MRI scan of the heart we aim to investigate how often, and in what way, the heart becomes damaged, and how the heart recovers 6 months later.

Who can participate?
Adults over 18 years, diagnosed with SARS-CoV-2 infection (COVID-19) with indication of heart damage (raised cardiac biomarker [Troponin]).

What does the study involve?
Patients will be required to have a cardiac MRI, an electrocardiogram (ECG) and to complete a 6 minute walk test and questionnaire at baseline and 6 months later. An optional blood test will also be taken for genetic and immunological testing.

What are the possible benefits and risks of participating?
MRI: A small proportion of patients do not tolerate MRI scanning due to claustrophobia, and patients who are known to be claustrophobic will therefore not be recruited. Some patients may experience claustrophobia once in the MRI scanner. Every effort will be made to reduce this sensation, as per normal clinical routine MRI scanning, but if a participant cannot tolerate the procedure the scan will be stopped immediately. Very rarely allergic reactions can occur (less than 1 in 3,000) but the department is equipped to manage allergic reactions if they happen.
6 minute walk test: Chairs will be placed at intervals to ensure the patient can stop and rest if required and the test will be performed with a Registered Nurse.
ECG: This is a non-invasive record of a heart tracing, patients are positioned on a bed and the test can take up to 15 minutes. Slight discomfort may be experienced when removing the sticker placed on the patient's chest or limbs.
Blood sample: A single blood sample will be drawn if the patient consents, patient can experience some discomfort during the procedure.
Confidentiality: The Sponsor will take reasonable steps to protect the confidentiality of information. Patients will be assigned a unique identifier number. Any participant records /images that are transferred to the University of Glasgow Clinical Trials Unit for analysis will contain the unique identifier only; participant names or any information which would make the participant identifiable will not be transferred.

Where is the study run from?
University of Leeds (UK)

When is the study starting and how long is it expected to run for?
April 2020 to August 2021.

Who is funding the study?
1. UK Research and Innovation
2. National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Prof. John Greenwood (scientific), j.greenwood@leeds.ac.uk
Kathryn Somers (public), kathryn.somers@nhs.net
Dr Laura Jones (public), l.m.jones@leeds.ac.uk

(added 10/05/2021)
Study duration and funding
The study is sponsored by the University of Leeds and is expected to run from 01/08/2020-31 /07/ 2021. The NIHR-BHF Cardiovascular Partnership have designated this project as a "COVID19 Cardiovascular Disease UK Flagship Project". The trial has been badged as an Urgent Public Health study by the NIHR and funding has been confirmed for NIHR CRN support approved by the UKRI-DHSC COVID-19 Rapid Response Rolling Call.

Contact information

Type(s)
Scientific

Contact name
Prof John Greenwood

ORCID ID
http://orcid.org/0000-0002-2861-0914

Contact details
University of Leeds and Leeds Teaching Hospitals NHS Trust
Dept. of Cardiology, X39
Leeds General Infirmary
Great George Street
Leeds
United Kingdom
LS1 3EX
+44 (0)1133925481
j.greenwood@leeds.ac.uk

Type(s)
Public

Contact name
Ms Kathryn Somers

Contact details
Department of Cardiology
Former Ward 39
Gilbert Scott Building
Leeds General Infirmary
Great George Street
Leeds
United Kingdom
LS1 3EX
+44 (0)113 3922358
kathryn.somers@nhs.net

Type(s)
Public

Contact name
Dr Laura Jones

Contact details
Leeds Institute of Cardiovascular and Metabolic Medicine
University of Leeds
Leeds
United Kingdom
LS2 9JT
+44 (0)7921121815
l.m.jones@leeds.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
285147

ClinicalTrials.gov number
Nil Known

Secondary identifying numbers
CD20/133244, IRAS 285147

Study information

Scientific Title
Demographic, multi-morbidity and genetic impact on myocardial involvement and its recovery from COVID-19: the COVID-HEART study

Acronym
COVID-HEART study

Study objectives
To describe the prevalence and extent of heart muscle injury in patients with COVID-19 and determinants (blood biomarkers, severity of acute infection, genetics, and comorbidities) of adverse clinical outcome in this population.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/06/2020, North West - Greater Manchester South Research Ethics Committee, (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8063; gmsouth.rec@hra.nhs.uk), ref: 20/NW/0292

Study design
Multi-centre observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Assessment of heart muscle damage secondary to coronavirus disease (COVID-19) in a hospitalised-recovering patient population (or those recently discharged) with raised cardiac biomarkers (troponin)

Interventions
Current interventions, as of 10/05/2021:

Firstly, we will establish a de-identified national image repository for all heart MRI scans already performed clinically in patients with COVID-19 infection (work package 1, WP1). We will seek consent from patients in multiple NHS hospitals with moderate to severe laboratory confirmed COVID-19 infection (defined as those requiring hospital admission for >2 days or needing ventilatory assistance) to use their images in the repository. Patients will also be invited to participate in the rest of the study (WP2).

For WP2 we will enroll patients with COVID-19 infection who have had an electrocardiogram (ECG) for clinical reasons and/or a blood test that has indicated heart muscle injury (and any participant sites from WP1 that choose to participate in the main research rest of the study). Participants will have an MRI scan (if they haven't already), complete a quality of life

questionnaire and have a six-minute walk test. Patients will be required to give written consent for their original ECG data to be used for the study and to participate in this work package. This will enable us to investigate how often, and in what way, the heart becomes damaged. Patients will also be asked to provide (with additional consent) an optional blood sample for genetic and immunological testing. Assuming the mean prevalence of heart muscle injury is 12 % (from previous studies) with a precision of 3.5 %, 95 % confidence level and a 10 % drop out rate, 370 patients would be required for this work package.

All participants for WP2 will be invited for a follow up visit 6 months later and will undergo a repeat ECG, heart MRI scan, an assessment of validated quality of life questionnaires and six minute walk test. This will allow us to assess how heart muscle damage and recovery is affected by age, sex, ethnicity and other medical conditions (such as diabetes, high blood pressure, heart disease and narrowing of blood vessels), as these are also known to be associated with high death rates. From the baseline heart MRI scans we will also seek to improve the bedside diagnosis of viral myocarditis heart muscle injury from a standard 12 lead ECG (which can have marked similarities to heart attack), by comparing these to a contemporary, UK, clinical trial ECG dataset of patients with acute following heart attack dataset as the reference standard (data already acquired and available).

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Intervention Type

Mixed

Primary outcome measure
Effect of COVID-19 on the heart at baseline and 6 months:
1. Heart abnormalities assessed using MRI
2. Heart rhythm and electrical activity assessed using ECG
3. Walking ability assessed using 6-min walking test
4. Patient-reported health status assessed using SF-36
5. Health-related quality of life assessed using EQ-5D

Secondary outcome measures
The influence of comorbidities, age, and genetics measured using medical records monitored from baseline up to 1 year (an optional blood test will be performed at baseline for genetic and immunological testing)

Overall study start date
16/04/2020

Completion date
31/07/2022

Eligibility

Key inclusion criteria
1. Aged ≥ 18 years
2. Diagnosed with SARS-CoV-2 infection with a raised cardiac biomarker (Troponin)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
370

Total final enrolment
386

Key exclusion criteria
1. Unable/unwilling to consent
2. Significant renal impairment (eGFR<30ml/min/m^2)
3. Female participants who are pregnant, lactating or planning pregnancy during the course of the study

4. Contraindications to MRI (pacemaker, intra-orbital debris, intra-orbital debris, intra-auricular implants, intracranial clips, severe claustrophobia
5. Known hypersensitivity to gadolinium-based contrast agents

Date of first enrolment
01/08/2020

Date of final enrolment
27/04/2021

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

Study participating centre
Leeds General Infirmary
Leeds Teaching Hospital Trust
Great George Street
Leeds
United Kingdom
LS1 3EX

Study participating centre
Gartnavel Royal Hospital
NHS Greater Glasgow and Clyde
1055 Great Western Road
Glasgow
United Kingdom
G12 0XH

Study participating centre
Leicester Royal Infirmary
University Hospital of Leicester NHS Trust
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Study participating centre
John Radcliffe Hospital
Oxford University Hospital NHS Foundation Trust
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
University Hospitals Bristol NHS Foundation Trust
Trust Headquarters
Marlborough Street
Bristol
United Kingdom
BS1 3NU

Study participating centre
Royal Free Hospital
Royal Free London NHS Foundation Trust
Pond Street
London
United Kingdom
NW3 2QG

Study participating centre
Edinburgh Royal Infirmary
NHS Lothian
51 Little France Cres
Edinburgh
United Kingdom
EH16 4SA

Study participating centre
The Royal London Hospital
Barts Health NHS Trust
80 Newark Street
London
United Kingdom
E1 2ES

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
St. Thomas Hospital
Guy's and St. Thomas' NHS Foundation Trust
Westminster Bridge Road
London
United Kingdom
SE1 7EH

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

Study participating centre
Royal Brompton Hospital
Royal Brompton & Harefield NHS Foundation Trust
Sydney Street
London
United Kingdom
SW3 6NP

Study participating centre
Aberdeen Royal Infirmary
NHS Grampian
Polwarth Building
Health Sciences Building
Foresterhill
Aberdeen
United Kingdom
AB25 2ZD

Study participating centre
Southampton General Hospital
University Hospital Southampton NHS Foundation Trust
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Liverpool Heart and Chest Hospital NHS Foundation Trust
Thomas Drive
Liverpool
United Kingdom
L14 3PE

Study participating centre
Queen Elizabeth Hospital
University Hospital Birmingham NHS Foundation Trust
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2GW

Study participating centre
Pindersfields Hospital
Mid Yorkshire Hospitals NHS Trust
Aberford Road
Wakefield
United Kingdom
WF1 4DG

Study participating centre
Royal Devon and Exeter Hospital
Royal Devon and Exeter Hospital NHS Foundation Trust
Barrack Rd
Exeter
United Kingdom
EX2 5DW

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

Study participating centre
North Tyneside Hospital
Northumbria Healthcare NHS Foundation Trust
Rake Lane
North Shields
United Kingdom
NE29 8NH

Study participating centre
Hammersmith Hospital
Imperial College Healthcare NHS Trust
Du Cane Road
London
United Kingdom
W12 0HS

Study participating centre
Royal Brompton Hospital
Royal Brompton and Harefield NHS Foundation Trust
Sydney Street
London
United Kingdom
SW3 6NP

Study participating centre
Freeman Hospital
Newcastle Upon Tyne Hospitals NHS Foundation Trust
Newcastle
United Kingdom
NE7 7DN

Study participating centre

St George’s University of London Hospital
St George’s University Hospitals NHS Foundation Trust
Cranmer Terrace
Tooting
London
United Kingdom
SW17 ORE

Study participating centre
Aintree University Hospital
Liverpool University Hospitals NHS Foundation Trust
Lower Lane
Liverpool
United Kingdom
L9 7AL

Study participating centre
Morriston Hospital
Swansea Bay University Health Board
Heol Maes Eglwys
Swansea
United Kingdom
SA6 6NL

Study participating centre
University Hospital Lewisham
Lewisham and Greenwich NHS Trust
Lewisham High Street
London
United Kingdom
SE13 6LH

Sponsor information

Organisation
University of Leeds

Sponsor details
Faculty Research Office
Room 9.29, Level 9
Worsley Building

Leeds
England
United Kingdom
LS2 9NL
+44 (0)1133437587
governance-ethics@leeds.ac.uk

Sponsor type
University/education

Website
http://www.leeds.ac.uk/

ROR
https://ror.org/024mrxd33

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
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

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/07/2023

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		10/06/2021	14/06/2021	Yes	No
Results article		27/01/2023	30/01/2023	Yes	No
HRA research summary			28/06/2023	No	No
Results article		14/08/2024	02/09/2024	Yes	No