ISRCTN12154994 https://doi.org/10.1186/ISRCTN12154994

Investigating the impact of coronavirus infection (COVID-19) on cardiovascular injury using multiple imaging methods

Submission date
14/07/2020

Recruitment status
No longer recruiting

Registration date
14/08/2020

Overall study status
Completed

Last Edited
15/09/2022

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
The number of people diagnosed with the coronavirus (COVID-19) infection has surpassed 8 million worldwide claiming over 500,000 deaths. Patients with underlying cardiovascular diseases (diseases of the heart and blood vessels) are more severely affected, with one in three patients showing evidence of heart injury. and have a substantially higher death rate from the virus.

Currently, the underlying mechanism for heart injury in patients with COVID-19 is uncertain. Heart complications from COVID-19 is an important cause of both disability and death. A better understanding of the impact of COVID-19 on cardiovascular health in African populations is urgently needed. Firstly, recent reports have indicated that people of African origin are disproportionately affected and experience the most severe manifestations of infection. Second, the prevalence of high blood pressure and additional risk factors such as HIV are much higher in sub-Saharan Africa and may impact overall rates of disability and death. Third, health systems in sub-Saharan Africa require data to guide future treatments to avoid short- and long-term consequences of COVID-19 on the cardiovascular health of populations.

Who can participate?
Adult patients with COVID-19

What does the study involve?
The study will investigate structural and functional changes of the heart muscle and arteries using various imaging techniques (known as a combined CT coronary angiogram /fluorodeoxyglucose (FDG) PET scan and a cardiac MRI scan) to evaluate evidence of inflammation, scarring in the heart muscle and prevalence of underlying blockage in the arteries supplying the heart. Blood testing will be also undertaken to measure markers of heart injury, strain, and general inflammation in the blood.

What are the possible benefits and risks of participating?
The possible benefits are from closer medical supervision and the scan may identify important

findings. However, there may be no direct benefit from participating in this study. Importantly, participating in clinical research may provide benefit to the wider population.

It is not thought that there are many disadvantages; however, as with any medical procedure or medication there are some risks. Performing the PET and CT scans will expose patients to a small dose of radiation. The amount of radiation varies but is around 7 times the amount individuals would normally receive in a year from background natural sources of radiation. There is also a very low risk of impairment of kidney function. This risk will be further minimised by excluding patients who have significant kidney disease.

Where is the study run ?
Aga Khan University Hospital (Kenya)

When is the study starting and how long is it expected to run for?
From March 2020 to March 2021

Who is the funding from?
The global challenges research fund, University of Edinburgh (UK)

Who is the main contact?
1. Dr Anoop Shah
anoop.shah@lshtm.ac.uk
2. Dr Shirjel Alam
shirjel.alam1@nhs.uk

Contact information

Type(s)
Scientific

Contact name
Dr Shirjel Alam

ORCID ID
https://orcid.org/0000-0002-2099-612X

Contact details
Southmoor Rd
Roundthorn Industrial Estate
Wythenshawe
Manchester
United Kingdom
M23 9LT
+44 (0)161 998 7070
shirjel.alam1@nhs.uk

Type(s)
Scientific

Contact name
Dr Anoop Shah

ORCID ID
https://orcid.org/0000-0002-2825-3419

Contact details
Room 249
London School of Hygiene and Tropical Medicine
Keppel Street
London
United Kingdom
WC1E 7HT
+44 (0)7766544156
anoop.shah@lshtm.ac.uk

Additional identifiers

Protocol serial number
2020/IERC-74

Study information

Scientific Title
CardiOvaScular Mechanisms In Covid-19 (COSMIC-19): A multimodality imaging study

Acronym
COSMIC-19

Study objectives
The mechanisms and pathological sequelae of Covid-19 induced cardiovascular injury can be identified by multi-modality imaging.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/06/2020, Nairobi Institutional Ethics Review Committee (IERC) (3rd Parklands Avenue, off Limuru Road, P.O. Box 30270, GPO 00100, Nairobi, Kenya; +254 203662107/2109; research.support@aku.edu), ref: 2020/IERC-74 (v2)

Primary study design
Observational

Study design
Single-centre observational cross-sectional multimodality imaging and biomarker study

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied

Cardiovascular injury (primary inflammatory, ischaemic, or secondary to systemic pathophysiology) in the context of COVID-19 infection

Interventions
Participants with confirmed COVID-19 will undergo biomarker analysis, using Troponin, Brain Natriuretic Peptide (BNP), and C-Reactive Protein (CRP) to assess for evidence of cardiovascular injury.

A subgroup of 30 participants with confirmed COVID-19 will be recruited, so that 20 patients with evidence of heart injury, and 10 patients without are included in the study. Study participants will undergo a combined CT coronary angiogram/flurodeoxyglucose (FDG) PET scan and a cardiac MRI scan as part of the study.

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)
Proportion of COVID-19 patients with evidence of cardiovascular injury measured using CT, CMR, or FDG-PET scan within 2 weeks of admission

Key secondary outcome(s)
Explore mechanisms of cardiovascular injury associated with COVID-19 measured using CT, CMR, or FDG-PET scan within 2 weeks of admission

Completion date
01/03/2021

Eligibility

Key inclusion criteria
1. COVID19 positive test within the previous 2 weeks (can be extended to 4 weeks at the investigator's discretion)
2. Aged ≥18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Prior diagnosis of myocardial infarction
2. Requiring invasive or non-invasive ventilation
3. Previous coronary revascularisation or cardiac surgery
4. Unable to undergo CT or CMR scanning, due to severe renal failure (estimated glomerular filtration rate <30 ml/min) or major allergy to iodinated contrast media /gadolinium
5. Pregnancy or breast feeding
6. Unable to give informed consent
7. Contraindication to imaging example metal fragments in the eye

Date of first enrolment
29/06/2020

Date of final enrolment
01/03/2021

Locations

Countries of recruitment
Kenya

Study participating centre
Aga Khan University Hospital
3rd Parklands Avenue off Limuru Road
PO Box 30270
Nairobi
Kenya
GPO 00100

Sponsor information

Organisation
The Aga Khan University Hospital

ROR
https://ror.org/03rppv730

Funder(s)

Funder type

Research organisation

Funder Name
UK Research and Innovation

Alternative Name(s)
UKRI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Anoop Shah (Anoop.shah@lshtm.ac.uk). Type of data: baseline characteristics, analysed imaging data, and biochemical data. When the data will become available and for how long: following publication and in perpetuity. By what access criteria data will be shared including with whom, for what types of analyses, and by what mechanism: For secondary analysis in collaboration with primary research team and shared via email. Whether consent from participants was obtained: Yes. Comments on data anonymisation: All data is anonymised and identifiable data removed.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/09/2022	15/09/2022	Yes	No
Protocol article		08/05/2021	11/05/2021	Yes	No
Preprint results	non-peer-reviewed protocol in preprint	01/10/2020	17/03/2021	No	No