

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 14/08/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 15/09/2022	Condition category Circulatory System	<input type="checkbox"/> 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?

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Contact information

Type(s)

Scientific

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Additional identifiers**EudraCT/CTIS number**

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

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)

Study design

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

Primary study design

Observational

Secondary study design

Cross sectional 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

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 measure

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

Secondary outcome measures

Explore mechanisms of cardiovascular injury associated with COVID-19 measured using CT, CMR, or FDG-PET scan within 2 weeks of admission

Overall study start date

23/03/2020

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

50

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

Sponsor details

3rd Parklands Avenue,
Limuru Road
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GPO 00100
+254 203662107
research.supportea@aku.edu

Sponsor type

Hospital/treatment centre

Website

<http://www.agakhanhospitals.org/nairobi/>

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

Results and Publications

Publication and dissemination plan

The results of this study will be written up as an academic research project and will be submitted for publication within a medical journal. It is likely that the results will also be presented at academic meetings or conferences.

Intention to publish date

01/02/2022

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?
Preprint results	non-peer-reviewed protocol in preprint	01/10/2020	17/03/2021	No	No
Protocol article		08/05/2021	11/05/2021	Yes	No
Results article		14/09/2022	15/09/2022	Yes	No