Clinical Characterisation Protocol

Training for Site Staff

ALERRT

African coaLition for Epidemic Research, Response and Training

ISARIC

Notes on this presentation

Guidance/suggested wording is provided in [blue text] and should be modified before the final presentation is given to any staff members

Background

- A novel coronavirus-induced disease was identified in Wuhan, China (COVID-19)
- [Consider providing a description in the context of local / country level]
- Symptoms vary from none to severe pneumonia in a minority

- This is an observational study, using data collected routinely as a part of clinical care
- For the collection of data and biological samples in a globally harmonised manner

Overview of the Protocol

Inclusion Criteria

Children and adults with suspected or confirmed novel Coronavirus (COVID-19) infection

Data Collection (Tier 0 to Tier 3)

- ISARIC/WHO COVID-19 Case Report Form (paper CRF or web-based electronic "eCRF") to be completed e.g. the COVID-19 Core CRF, or the RAPID CRF
- Depending on local resources, interest and feasibility, chose which tier to use
- Sites are encouraged to enter data using the eCRF(s)

Tier 0

Patient data (CRF)

Sampling (Tier 1 to Tier 3)

Read the Clinical Characterisation Protocol to make an assessment to decide if you have the resources and capacity to do: Sampling on enrolment (Tier 1) and / or Serial Sampling (Tier 2 or 3)

Tier 1

Patient data (CRF)

Single Biological Sample

Tier 2

Patient data (CRF)

Serial Biological Sampling

Tier 3

Patient data (CRF)

Population Pharmacokinetics of antimicrobials & immune modulators

Aims of the study (1/2)

Primary objectives

- Describe the clinical features of COVID-19 and identify risk factors
- Describe, where appropriate, the response to treatment, including supportive care and novel therapeutics

[In addition, depending whether you are operating to Tiers 1, 2, 3 - please delete as appropriate]

- Observe, where appropriate and feasible, pathogen replication, excretion and evolution, within the host, and identify determinants of severity and transmission using high-throughput sequencing of pathogen genomes obtained from respiratory tract, blood, urine, stool, CSF and other samples
- Characterise, where appropriate and feasible, the host responses to infection and therapy over time, including innate and acquired immune responses, circulating levels of immune signalling molecules and gene expression profiling in peripheral blood
- Identify host genetic variants associated with disease progression or severity
- Understand transmissibility and the probabilities of different clinical outcomes following exposure and infection

Aims of the study (2/2)

Secondary objectives

- Facilitate effective triage and clinical management of patients with COVID-19
- Develop clinical guidance documents and offer clinical recommendations to policy makers on the basis of evidence obtained

[In addition, depending whether you are operating to Tiers 1, 2, 3 - please delete as appropriate]

- Determine infectivity and inform appropriate infection control measures of the various pathogens

Eligibility

- All adult and children with proven or suspected COVID-19, admitted to hospital should be considered for the study

- Participants should be enrolled assuming

    1. All eligibility criteria are met; and

    1. Patient or their guardian etc. has given their consent to participate in the study [Note: consent may not be required for Tier 0, Data Collection only]

All documents available in the Study Master File, found [provide details of location]

The Patients Journey (1/2)

- [Details about a 'dedicated isolation room', for treating, consenting, samples collection etc.]

The Patients Journey (2/2) continued…

- Safety points e.g. PPE is available at facility
- Online training materials for PPE use:

  ✓ UK National Health Service:
  https://www.youtube.com/watch?time_continue=2&v=kKz_vNGsNhc&feature=emb_title

  ✓ Public Health England:
  https://www.gov.uk/government/publications/wuhan-novel-coronavirus-infection-prevention-and-control/covid-19-personal-protective-equipment-ppe

  ✓ World Health Organization:
  https://apps.who.int/iris/bitstream/handle/10665/331695/WHO-2019-nCov-IPC_PPE_use-2020.3-eng.pdf

  OPEN WHO, COVID-19: How to put on and remove personal protective equipment (PPE):
  https://openwho.org/courses/IPC-PPE-EN

  ✓ Centers for Disease Control and Prevention:
  https://www.cdc.gov/coronavirus/2019-ncov/hcp/using-ppe.html

Screening & Study Enrolment; Participant Information Sheet (1/3)

- The patient, or the patient's carer/guardian, should be provided with a 'Participant Information Sheet' and allowed to read and ask any questions

- Ensure that the patient, or the patient's carer/guardian, has had time to ask any questions (they may be scared)

- They must understand that participation is voluntary – they can stop at any time, and request that any samples or information collected can be destroyed

    - If they do not enter the study they understand that it will not affect they way that they doctors will treat them – they still receive the best care currently available

- All information about the patient will be kept private. Only the people responsible for their care and for this study will know that they were involved in this study

    - No personal details i.e. name, date of birth etc. are collected

- Their data will be stored [on a computer/in a filing cabinet], and will be kept secure. [Provide details on the duration that the data will be kept]

Screening & Study Enrolment; Informed Consent Form (2/3)

[Insert picture of an example consent form]

Clinical characterization and preparedness for COVID-19 disease

INFORMED CONSENT FORM FOR ADULT PATIENT

	Please initial box
I have read (or it has been read to me) the information sheet for this study dated 1st February 2020, version 3.1. I understand the information and have had the opportunity to ask questions for clarification.	
I understand that my participation is voluntary and that I am free to withdraw from the study at any time, without giving any reason and without my medical care or rights being affected.	
I understand that data will be collected from my medical records, including medications and laboratory results by study staff during the study. I agree that these individuals may have access to my research records and their study results.	
I understand that data collected during the study may be looked at by regulatory authorities, authorised individuals from Kumasi Center for Collaborative Research in Tropical Medicine and the GHS, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	
I understand that if samples are taken laboratory results from samples collected during the study will be reported to study staff. This information may be looked at by regulatory authorities, authorised individuals from Kumasi Center for Collaborative Research in Tropical Medicine and the GHS. I agree that these individuals may have access to my research records and study results.	
I understand that my information can be collected, analysed, reported and shared with others within and outside Africa as part of this study. I understand that my name will not be used and I will not be identified.	
I agree that my fully anonymized samples may be sent elsewhere in the world to be analysed.	
I agree that Genetic material from my blood sample will be analysed to determine whether any genetic factors have made me susceptible to severe infection. OR IF YOU DO NOT AGREE, TICK HERE ☐	

If they are willing then they should complete the Informed Consent Form and either sign, or provide a thumbprint where requested

If participant can give consent, but is unable to read, then a witness countersigns the form to indicate that the consent process was informed

Some patients will be too ill to give informed consent

- In this situation, provide Participant Information Sheet to legal representative (e.g. close relative, friend or doctor not involved in the study)

Person receiving consent should complete their section as indicated on the form

Screening & Study Enrolment; Children, (3/3)

- Children <12 years of age should be provided with the 'younger' children information leaflet and this should be read along with their parent(s)/carer/guardian
    - The parent/guardian should sign the consent form (or provide a thumbprint)
- Children aged 12-16 years of age should be provided with the relevant information sheet and the child given the opportunity to sign the information sheet (or provide a thumbprint) to indicate their assent if they are well enough and signature is possible
    - The parent / guardian should sign (or provide a thumbprint on) the consent form (witnessed consent)
- Young people aged >16 years should be provided with the 'adult' information sheet and they should sign (or provide a thumbprint on) the consent form (or witnessed consent used)
- [Witnessed consent may be obtained over the if hospital visiting rules or parental infection mean a parent/guardian cannot be physically present]

Screening & Study Enrolment; Sampling

Laboratories and samples (skip if working to Tier 0 only)

- [Outline laboratory biosafety procedures and the appropriate BSL2, BSL3 or BSL4 safety management and guidelines (dependent on local/national guidelines)]
- [Outline the procedures for serial sampling, including the appropriate timings of serial samples, depending on the locally adapted protocol (Tiers 2 or 3)]
- [Outline the procedures for biological sample processing involving manual techniques and/or use of laboratory equipment, depending on the locally adapted protocol]
- [Provide an outline/overview of sample processing, including sample handling and labelling]

Completion of Data Collection Forms

[Describe how to complete the data collection form; if you are using the ISARIC tools – there are two forms to chose from, and a link to the guidelines are provided below]

Core CRF completion guide:
https://media.tghn.org/medialibrary/2020/05/ISARIC_WHO_nCoV_CORE_CRF_Completion_Guide_23APR20.pdf

Rapid CRF completion guide:
https://media.tghn.org/medialibrary/2020/04/ISARIC_COVID-19_RAPID_CRF_Completion_Guide_24MAR20.pdf

Entering data using the eCRF

[If you are using the ISARIC Data Platform – there are two eCRFs, the Core and the Rapid; Links to the data entry guides are provided below]

Core CRF completion guide:
https://media.tghn.org/medialibrary/2020/03/ISARIC_nCoV_Data_Entry_Guide.pdf

Rapid CRF completion guide:
https://media.tghn.org/medialibrary/2020/04/ISARIC_COVID19_RAPID_Data_Entry_Guide.pdf

Thank you

Please contact [name and contact details of the Principal Investigator]

Partners supporting research preparedness and response