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A Saudi Arabia based study into the impact of coronavirus infection on the nervous system

Submission date	Recruitment status	[_] Prospectively registered
07/06/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/06/2020	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
04/05/2022	Infections and Infestations	[_] Record updated in last year

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. COVID-19 is a threat to global health and has been classified by the WHO as a pandemic. At the time of writing, June 2020, COVID-19 is spreading rapidly within the Kingdom of Saudi Arabia with almost 60,000 confirmed cases. COVID-19 targeted hospitals have been deployed by the Ministry of Health (MOH) to deal with the pandemic.

Current understanding of COVID-19 infection is that the virus can infect the respiratory (breathing) system. Some people do not have symptoms but can carry the virus and pass it on to others. Other signs and symptoms caused by the virus are not yet well understood or known. A small number of patients may develop a severe case of the disease which requires intensive care unit admission. In these severe cases, patients can develop multi-system organ failure, acute respiratory failure, and altered level of consciousness. Although there is not yet much data on the impact of COVID-19 on the nervous system, there have been reported cases of various neurological (nervous system) outcomes, ranging from peripheral neuropathies (a type of nerve damage that can cause pain, numbness or weakness, typically in the hands and feet) to central nervous system involvement (i.e. stroke).

There is a lack of data on the possible neurological outcomes caused by COVID-19 and what the risk factors for those might be.
This study based in the Kingdom of Saudi Arabia aims to explore the possible neurological outcomes of COVID-19 in adult patients. The study hopes to identify what the neurological outcomes of COVID-19 could be and how severe these outcomes are; to understand the processes of nervous system, and to explore what risk factors may make these outcomes more likely.

Who can participate?
Adult patients hospitalized with COVID-19

What does the study involve?
This is an observational study, there will be no additional changes for patients beyond standard care. In the event that a patient has neurological symptoms, these will be managed according to standard care and recorded for this study.

What are the possible benefits and risks of participating?
This is an observational study, so participants will receive standard care according to local guidelines. There are no additional anticipated risks as a result of taking part in this study.

Where is the study run from?
King Saud Medical City, Critical Care Department and Neurocritical Care Unit (Saudi Arabia)

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

Who is funding the study?
King Saud Medical City (Saudi Arabia)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
KSMC, IRB, H1RI-24-May20-01

Study information

Scientific Title
Saudi Arabia study for the Neurological manifestations in COVID-19 (SANCO): a retrospective /prospective observational study into nervous system involvement after infection with SARS-CoV-2 (COVID-19)

Acronym
SANCO

Study objectives
We aim on investigating the spectrum, severity, and outcome of nervous system manifestations in COVID-19 in the Kingdom of Saudi Arabia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/06/2020, King Saud Medical City Institutional Review Board (Riyadh 12714-3232 Saudia Arabia, +966 435-5555 Ext. 2345; irb@ksmc.med.sa), ref: H1RI-24-May20-01

Study design
Retrospective/prospective observational cohort study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Neurological manifestations in COVID-19 (SARS-CoV-2 infection) patients.

Interventions
This trial will integrate a mixture of retrospective and prospective data collection, with a follow-up period of 6 months. Patients admitted to the hospital from March 2020 until the start of prospective recruitment (24/05/2020) will be included retrospectively.

Neurologic manifestations will be reviewed and confirmed by two trained neuroscientists. Major disagreement between 2 reviewers will be resolved by consultation with a third one. Neurologic manifestations will be categorized into 3 categories: central nervous system (CNS) manifestations (dizziness, headache, impaired consciousness, acute cerebrovascular disease, ataxia, and seizure); peripheral nervous system (PNS) manifestations (taste impairment, smell impairment, vision impairment, and nerve pain); and skeletal muscular injury manifestations. Impaired consciousness includes the change of consciousness level (somnolence, stupor, and coma) and consciousness content (confusion and delirium).

In cases of suspected meningoencephalitis/encephalopathy lumbar puncture (LP) is usually integrated in the diagnostic work-up; hence, RT-PCR for COVID-19 will be also performed in the CNS accordingly. In KSA, no autopsies are currently performed according to legislation thus there will be no means to examine any possible brain specimens from deceased cases.

Acute cerebrovascular disease includes ischemic, thrombotic stroke and cerebral hemorrhage diagnosed by clinical symptoms and head CT. Seizure is based on the clinical symptoms at the time of presentation. Skeletal muscle injury was defined as when a patient had skeletal muscle pain and elevated serum creatine kinase level greater than 200U/L.

Comorbid disorders (i.e., diabetes, hypertension, renal failure, coagulopathies, autoimmune syndromes, hypercoagulable states, malignancies, previously known neurological disorder) which may influence the clinical picture will be registered and analyzed accordingly per individual case scenario.

Intervention Type
Other

Primary outcome(s)
1. Incidence of neurological manifestations in COVID-19 hospitalized patients measured using neurological examination and other pertinent paraclinical examinations, tests, and questionnaires (i.e., total blood count, biochemistry, screening for systemic disorders and hypercoagulable states, imaging such as brain computed tomography scans and magnetic resonance imaging studies, other tests such as cerebrospinal fluid analysis, electromyography, biopsies, etc.) collected from medical records at baseline, on hospital discharge, and 6 months follow-up
2. Range of symptoms of neurological manifestations in COVID-19 hospitalized patients measured using neurological examination and other pertinent paraclinical examinations, tests, and questionnaires collected from medical records at baseline, on hospital discharge, and 6 months follow-up
3. Severity of neurological manifestations in COVID-19 hospitalized patients neurological examination and other pertinent paraclinical studies such as imaging studies (CT, MRI, etc.) collected from medical records at baseline, on hospital discharge, and 6 months follow-up

Key secondary outcome(s))
1. Consciousness and neurological picture measured using the GlasgoW Coma Scale (GCS) and neurological examination at baseline, hospital discharge, and at 6 months follow-up
2. Organ function status measured using the Sequential Organ Failure Assessment (SOFA) Score at baseline and hospital discharge
3. Markers of cytokine release syndrome measured through changes in laboratory inflammation markers (lymphocyte count, serum levels of C-reactive protein, lactate dehydrogenase, interleukin-6, ferritin, and d-dimer in addition to other common laboratory markers total blood count, coagulation profile, and biochemistry panel) at baseline and hospital discharge
4. Extent of inflammation measured through changes in laboratory inflammation markers at baseline and hospital discharge
5. Evolution of neurological disorders measured through changes in imaging studies (brain MRI for stroke or encephalitis, and other pertinent tests such as electromyography to measure the evolution of peripheral nervous system disorders) at baseline and hospital discharge
6. ICU length of stay assessed from medical records collected at baseline and ICU discharge
7. Number of days on mechanical ventilation assessed from medical notes collected at 6 months
8. 28 days and 3 months mortality assessed from medical notes collected at 28 days and 3 months
9. Functional outcomes and degree of disability measured using the Glasgow Outcome Score Extended (GOSE) and the Modified Rankin Scale (MRS) at hospital discharge

Completion date

28/02/2021

Eligibility

Key inclusion criteria
1. Aged > 18 years
2. Hospitalized with COVID-19 as per the World Health Organization and Saudi Ministry of Health case definition

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Terminally ill receiving palliative care
2. Test negative for COVID-19

Date of first enrolment
24/05/2020

Date of final enrolment
30/08/2020

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
King Saud Medical
King Saud Medical City
Riyadh
Saudi Arabia
12714-3232

Sponsor information

Organisation
King Saud Medical City

ROR
https://ror.org/03aj9rj02

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
King Saud Medical City

Results and Publications

Individual participant data (IPD) sharing plan
The data will be available by the Primary Investigator, Dr. Abdulrahman Alharthy, email: a_almshal@hotmail.com, upon reasonable request, patient medical records, clinical and paraclinical data are stored in excell sheet in an anonymous manner, consent will be obtained, no other restrictions apply as this is an obervational study

IPD sharing plan summary
Available on request