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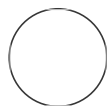
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COVID-19 is associated with increased morbidity and mortality in patients with chronic kidney disease (CKD) on dialysis. CKD requires particular emphasis during the pandemic due to concern for increased susceptibility to infection from greater use of health facilities in people undergoing maintenance hemodialysis. COVID-19 due to SARS-CoV-2 involves multiple organs and lung injury is one of the most clinical manifestations. The binding of SARS-CoV-2 to the ACE2 receptors at target cells, including type II pneumocytes, and alveolar macrophages in the lung could arise into acute systemic inflammatory responses and cytokine storm. The consequentially leading to lung-resident dendritic cells (rDCs) activation, T lymphocytes production and

Lung COVID

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DISCLAIMER

The authors declare no competing interests

ABSTRACT

Primary objectives:

-To study the Chest CT and pulmonary function tests in ESRD patients after recovered from COVID-19

Secondary objectives

- To study the factors affecting the pulmonary sequelae after COVID-19 in CKD patients such as oxygen requirement, ventilator need and levels of inflammatory cytokines such as interleukin-6 (IL-6) and C-reactive protein (CRP)

Type of study: Prospective observational cohort study

Inclusion Criteria:

CKD stage 5 requiring HD or continuous peritoneal dialysis (CAPD) for more than 3 months

- Age 18-80 years
- Diagnosis of COVID-19

lymphocytes production and release antiviral cytokines into the alveolar septa and interstitial compartments resulting in diffuse alveolar epithelium destruction, hyaline membrane formation, alveolar septal fibrous proliferation and pulmonary fibrosis. Although it has been reported that subgroups of COVID-19 survivors developed persistent lung parenchymal injury that persisted at least after 6 months [5-6], the data in CKD patients has not been reported yet. In addition, a study of pulmonary function test after COVID-19 is needed to be investigated. Thus, we plan to assess pulmonary sequelae of COVID-19 in hemodialysis (HD) patients and pulmonary function test after recovered of infection at least 3 months.

confirmed by real time polymerase chain reaction (RT-PCR) and recovered for more than 3 months previously

Exclusion Criteria:

- Patients with history of chronic lung diseases i.e chronic obstructive pulmonary disease (COPD) and restrictive lung disease

Criteria to withdraw from the protocol Patients who have active disease after enrollment

Participants 100 patients

Place- Faculty of Medicine, Vajira Hospital, Navamindradhiraj University

1. Objectives:

Primary objectives:

- To study the Chest CT and pulmonary function tests in ESRD patients after recovered from COVID-19

Secondary objectives

- To study the factors affecting the pulmonary sequelae after COVID-19 in CKD patients such as oxygen requirement, ventilator need and levels of inflammatory cytokines such as interleukin-6 (IL-6) and C-reactive protein (CRP)

6. Study design

6.1 Type of study

Prospective
observational cohort study

6.2 Inclusion,exclusion and criteria to terminate the study

ATTACHMENTS

[Trial Protocol Lung
Covid.docx](#)

Inclusion Criteria:

-
CKD stage 5 requiring HD
or continuous peritoneal
dialysis (CAPD) for more
than 3 months

-
Age 18-80 years

-
Diagnosis of COVID-19
confirmed by real time
polymerase chain reaction
(RT-PCR) and recovered
for
more than3 months
previously

Exclusion
Criteria:

-
Patients with history of
chronic lung
diseases i.e chronic
obstructive pulmonary
disease (COPD) and
restrictive lung
disease

Criteria to withdraw from
the protocol

- Patients
who have active disease
after enrollment

GUIDELINES

7. Sample size calculation

This study aimed to identify the prevalence of pulmonary abnormalities in both radiographic findings and PFT results after recovery from COVID-19 infection. We used the following equation for estimating an infinite population proportion:

where,
 n is the sample size

$Z_{\alpha/2}$ is
the area
under the normal curve

The significance
level for the
hypothesis was set to $\alpha = 0.05$; thus $Z_{\alpha/2} = 1.96$

d is the
acceptable error ($d = 0.10$)

p is
the prevalence
of lung abnormality,
defined as $p = 0.50$, that
yielded the maximum
sample size;
thus,

$$n = \frac{1.96^2 \times 0.50 (1 - 0.50)}{d^2}$$

The study was conducted according to the Declaration of Helsinki and Good Clinical

Practice guidelines, and all study methods were carried out in accordance with relevant guidelines and regulations. All patients participating in the study signed an informed consent before enrollment.

14. Expected outcomes of the study

This trial contribute to new knowledge, including the consequences of the most affected organ (lung) after COVID-19, which has rarely been reported previously. In addition, the factors that associated with poor pulmonary outcome will also be considered.

15. Dissemination of results and publication policy

The
data supporting the findings of this study are available from the corresponding author.

0.10^2

$n = 97$

We recruited 100 cases by convenience sampling from a population of end-stage kidney disease (ESKD) patients who had recovered from COVID-19 infection.

8. Methodology:

1. After written informed consent is obtained, we then collect demographic data and information regarding disease history, coexisting medical conditions, medication history, treatment during COVID-19 infection, including oxygen requirement, and laboratory data (complete blood count [CBC] and measurement of interleukin-6 [IL-6] and C-reactive protein [CRP] levels).

2. At least 3 months post COVID-19 infection, all patients will be evaluated for ongoing respiratory symptoms and undergo PFT and chest CT scans as followed:

Computed tomography technique

High-resolution computed tomography (HRCT) was performed in a single breath-hold on a 128-slice multidetector computed tomography (MDCT) scanner (Ingenuity 128; Philips Healthcare Nederland B.V, Netherlands). HRCT was performed with a 1-mm slice thickness with the patient in the supine position during

SAFETY WARNINGS



Safety considerations

The participants will have minimal effects from the measurements performed in this study. The anticipated side effects from radiation or pulmonary function tests will be closely monitored.

ETHICS STATEMENT

This trial was prospectively registered at ClinicalTrials.gov Identifier: NCT05348759

on 26/04/2022 and was approved by the institutional review board of the Faculty of Medicine, Vajira Hospital, Navamindradhiraj University, Bangkok, Thailand (COA 302/64)

in the supine position during end-inspiration and prone position during end-inspiration.

Computed tomography interpretation

Using a Picture Archiving and Communication System (PACS; EV Insite version 3.11.1.500; PSP Corporation, Japan), three radiologists with 9, 10, and 14 years of experience performed consensus interpretations blinded to the patients' clinical information. The readers assessed the presence of the following CT patterns; consolidation, ground-glass opacities (focal, multifocal, diffuse), mosaic attenuation patterns (hypoattenuating and hyperattenuating areas), perilobular consolidation (organizing pneumonia-like pattern), reticulations, architectural distortion, honeycombing, traction bronchiectasis, pneumatocele, curvilinear lines, nodules, and pleural thickening or pleural effusion.¹⁶ Additional findings were annotated separately. The distribution of the patterns was recorded as the upper lobe, middle lobe/lingual, or lower lobe. CT scores reflecting the extent of lobar involvement were obtained using a five-point scale (0: 0%, 1: <5%, 2: 5%-25%, 3: 26%-50%, 4: 51%-75%, 5: >75%; range, 0-5; global score, 0-25).

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Protocol status: Working
We use this protocol and it's working

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84501

- 1 Follow-up Study of the Pulmonary Function and CT scan finding in Chronic Kidney Disease Patients After COVID-19 Infection