**STUDY PROTOCOL**

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| TITLE | **STUDY OF THE SEQUELAE OF SEVERE ACUTE RESPIRATORY SYNDROME (SARS) CORONAVIRUS-2 (SARS-COV-2) DISEASE-2019 (COVID-19) IN SURVIVORS AT 3 YEARS** |
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| FELLOWSHIP APPLIED FOR | Sunpharma science foundation clinical research fellowship 2024 |
| YEAR OF APPLYING | 2024 |
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**INTRODUCTION**

After the acute phase of a severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) disease (COVID-19), a significant proportion manifest persistent somatic symptoms over weeks, months and even years (1), This condition called “long COVID” has also been referred to as “post-acute sequelae of COVID-19”, “post-COVID-19 syndrome”, “post-COVID conditions” or post-acute COVID-19 syndrome, among others. One of the characteristic features of long COVID-19 is that it affects survivors of COVID-19 at all disease severity. Data from all over the world show that around a third of people infected by SARS-CoV-2 may go on to develop symptoms that can be diagnosed as long COVID. As there are sparse published data regarding the long-term effects of COVID-19 at 3 years in survivors, the present study is planned.

**AIM AND OBJECTIVES**

**Aim**

To study the long-term sequelae of COVID-19 in the patients who had tested positive for COVID-19

**Objectives**

(i) To observe and document the long-term complications occurring in hospitalized and non-hospitalised COVID-19 survivors at 3 years; (ii) To observe and document the long-term clinical and radiographic changes in hospitalized and non-hospitalized COVID-19 survivors at 3 years.

**MATERIAL AND METHODS**

Patients (aged 18 years and above) who had tested positive for COVID-19 either by real time reverse transcriptase – polymerase chain reaction (rtRT-PCR) / rapid antigen test (RAT)/ TrueNat test and recovered will be screened for inclusion in the study over a period of 6 months. **Inclusion criteria**

(i) Adult patients (aged 18 years and above) who tested positive by rtRT-PCR/ RAT/ TrueNat for COVID-19 who were diagnosed to have and treated for COVID-19 at the SVIMS-SPMCWH-State COVID-19 Hospital, Tirupati and are alive at 3 years from the time of discharge.

**Exclusion criteria**

(i) Patients <18 years of age; (ii) Patients who have a history of other respiratory complaints, before they got tested positive for COVID-19 (tuberculosis, interstitial lung disease, influenza, hypersensitive pneumonitis); (iii) Subjects unwilling to participate in the study.

**Regulatory clearances**

The study will be initiated after obtaining clearance from the Institutional Ethics Committee.

**Informed consent**

Written informed consent will be obtained from study participants in whom physical interviews will be conducted. Verbal/online informed consent will be obtained from participants who will be telephonically interviewed.

**Study procedure**

A line-listing of records of patients who had tested positive for COVID-19 by rtRT-PCR / RAT/ TrueNat test and were discharged from the hospital will be obtained from the SVIMS – SPMCW State COVID-19 Hospital, Tirupati. These patients will be followed-up at 36 months or after their discharge from the hospital. At the time of initial presentation triaging and disease severity stratification was done as per the Ministry of Health and Family Welfare (MoHFW) guidelines (2), Government of India, as non-severe and severe COVID-19. Participants will be contacted through telephone. They will be subjected to a structured questionnaire. Verbal consent will be taken before enrollment. The questionnaire included details regarding demographics, symptoms at admission, method of diagnosis of COVID-19, status of co-morbid conditions, use of oxygen at admission or use of domiciliary oxygen, and asked if they had/were experiencing any unexplained symptoms after recovering from acute COVID-19 infection.

Participants will be asked systematically about symptoms pertaining to various body systems any other complaint. Study participants will be asked to attend a post-COVID-19 follow-up clinic at the institute. Participants who attend the clinic will undergo thorough general physical examination including pulse rate, blood pressure, and oxygen saturation as measured by pulse oximetry, and will be asked to repeat chest radiograph or CT chest at the institute (128–slice Siemens CT. Somatom Definition AS+, Siemens Healthcare, Germany) if they complained of breathlessness or if chest auscultation is abnormal. Other relevant investigations will be ordered according to their complaints. Details regarding the administration of the Bacillus-Calmette-Guerin (BCG) vaccine and COVID-19 vaccination, including type of vaccine and dosages of vaccination, and dates of vaccination will also be recorded, to check for vaccine breakthrough infection. Participants who are not willing to attend the post-COVID clinic will be asked to undergo repeat imaging (if needed) and forward the report (or films) via an internationally available, instant messaging platform.

**Statistical analysis**

Data will be recorded on a predesigned proforma and managed using a Microsoft Excel worksheet (Microsoft Corp. Redmond, WA). All the entries will be double-checked for any possible error. Descriptive statistics for categorical variables will be presented as percentages and for continuous variables as mean ± standard deviation; median (interquartile range) as appropriate. Data will be analyzed using statistical software IBM (International Business Machines Corporation) SPSS (Statistical Package for the Social Sciences) Version 26 (IBM Corp Somers NY, USA).

**ANTICPATED OUTCOMES**

The study will provide objective reliable data on the long-term clinical consequences in COIVD-19 survivors at 3years follow-up and these data will help in formulating rehabilitation programme for COIVD-19 survivors

**TIMELINES**

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| **Target** | **Time-line** |
| 1.Obtaining Institutional Ethics Committee (IEC) clearance | 1 month from date of award of Fellowship in the immediately ensuing IEC meeting. |
| 2. Data gathering | 3 months |
| 3. Data entry, data analysis, writing up the report | 2 months |
| Total duration | 6 months from date of award of Fellowship |

**REFERENCES**

1. Sharma SK, Mohan A, Upadhyay V. Long COVID syndrome: An unfolding enigma. Indian J Med Res 2024;159:585-600.

2. Ministry of Health and Family Welfare. Clinical management protocol: COVID 19. Available at URL:https://covid19dashboard.mohfw.gov.in/pdf/ClinicalManagementProtocolforCOVID19dated27062020.pdf. Accessed on November 29, 2024.