Clinical Trial Details (PDF Generation Date :- Fri, 16 Apr 2021 21:03:38 GMT)

CTRI Number	CTRI/2020/08/027285 [Registered on: 20/08/2020] - **Trial Registered Prospectively**
Last Modified On	21/08/2020
Post Graduate Thesis	No
Type of Trial	Observational
Type of Study	Cross Sectional Study
Study Design	Other
Public Title of Study	Safety of convalescent plasma (CVP) drawn from mild symptomatic COVID-19 patients.
Scientific Title of Study	Study to assess and establish safety of convalescent plasma (CVP) drawn from mild symptomatic COVID-19 patients.

Secondary IDs if Any

Secondary ID	Identifier
NIL	NIL

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
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Source of Monetary or Material Support

Source of Monetary or Material Support
> AIIMS

Primary Sponsor

Primary Sponsor Details	
Name	AIIMS
Address	Ansari Nagar, New Delhi-110029
Type of Sponsor	Research institution and hospital

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Diptiranjan Rout	Dept. of Transfusion Medicine, AIIMS	Ansari Nagar, New Delhi-110029 South DELHI	08727804293 drdiptiranjanrout@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
AIIMS	Approved	30/06/2020	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	Coronavirus as the cause of diseases classified elsewhere

Intervention / Comparator Agent

Type	Name	Details

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	65.00 Year(s)
Gender	Male
Details	a) Anyone aged >18 years and <65 years; b) Males; c) Body weight: >50 kg; d) Patients with complete seroconversion; e) Written informed consent to participate in the study. f) Confirmed previous SARS CoV-2 infection with mild symptomatology limited to: 1) cough, 2) fever, 3) myalgia, 4) sore throat, 5) chest pain or pressure, 6) congestion, 7) headache 8) diarrhoea, 9) nausea, and 10) loss of taste or smell.

Exclusion Criteria

Exclusion Criteria	
Details	a) Anyone aged 65 years; b) Females; c) Any comorbid conditions like Diabetes mellitus (uncontrolled), Hypertension (Uncontrolled), Asthma or any other respiratory conditions; d) Patients of COVID-19 with moderate and/ or severe symptomatology; e) Patients with no seroconversion; f) Patients with incomplete seroconversion; g) Failure to obtain Written informed consent; h) Known cases of any malignancy (Cancer COVID-19).

Method of Generating Random Sequence	Not Applicable
Method of Concealment	Not Applicable
Blinding/Masking	Not Applicable

Primary Outcome

Outcome	Timepoints
To establish seroconversion in mild symptomatic COVID-19 patients and thence, to establish the safety of the convalescent plasma drawn from such patients for the therapeutic usage in other patients.	6 months

Secondary Outcome

Outcome	Timepoints
a) To establish the baseline titer of the convalescent plasma drawn from mild symptomatic COVID-19 patients. b) To establish the highest serological dilution which can be effectively used to capture the SARS-CoV-2 antigens. c) To establish the absence of SARS-CoV-2 RNAemia in the drawn convalescent plasma. d) To predict a serological marker to identify potential CVP donors among the recovered patients of mild COID-19.	6 months

Target Sample Size	**Total Sample Size=**100 **Sample Size from India=**100 **Final Enrollment numbers achieved (Total)=**Applicable only for Completed/Terminated trials **Final Enrollment numbers achieved (India)=**Applicable only for Completed/Terminated trials
Phase of Trial	N/A
Date of First Enrollment (India)	21/08/2020
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**6 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Open to Recruitment
Publication Details	NIL

Brief Summary

The coronavirus disease 2019 (COVID-19) is now a worldwide pandemic caused by the severe acute respiratory virus coronavirus 2 (SARS-CoV-2) which originated from Wuhan, China in 2019. To date, no specific treatment has been proven to be effective for COVID-19. With the recent rapid evolution of COVID-19 pandemic in India, no effective treatment and the currently observed mortalities, it is about time to consider the role of convalescent plasma (CVP) in addition to various existing measures to limit and control the infection. Convalescent plasma (CVP), obtained by collecting whole blood or plasma from a patient who has survived a previous infection and developed humoral immunity against the pathogen responsible for the disease in question, is a possible source of specific antibodies of human origin. Like blood donation programme around the world, identification, selection and recruitment of potential donors are challenging tasks. Besides, there are organizational and technological challenges in the collection, production and use of the products. The following important factors may be kept in mind when considering this treatment: (a) eligibility criteria of convalescent COVID-19 patients to donate whole blood or plasma, (b) pre-screening and pre-donation testing of convalescent COVID-19 donors; (c) criteria for collection of COVID-19 plasma; (d) post-donation treatment of plasma; and (e) recommendations for plasma transfusion. Though the CVP therapy from the pre-antibiotic era is a century old therapeutic modality, this is a naive therapy for the emerging COVID-19 in today's modern era of medicine. The knowledge regarding the SARS-CoV-2 is evolving every day and thence, the perception of community drifts accordingly. Patients who have recovered from COVID-19 are valuable donor source of CVP. Nevertheless, the balance between clinical benefits and associated risks of CVP in COVID-19 remains uncertain. The CVP contains the neutralising antibodies against the SARS-CoV-2 virus. The concentration of these neutralising antibodies are very important factor in deciding the dose of CVP to be transfused to the patients with COVID-19. However, inter donor variability of titer is a concern for establishing a uniform dosing for CVP transfusions. No study has been done so far in deciding upon a baseline neutralising titer in the CVP available from recovered patients. It is also postulated that the mild symptomatic COVID-19 patients will have poorer titers of neutralising antibodies in the CVP than the recovered patients with moderate and/ or severe COVID-19. However, a clinically efficacious baseline titer which may be

considered adequate enough to bring the therapeutic response in patients of COVID-19, is yet to be elucidated. Thence, this study is planned to look for the baseline neutralising titers of Anti-SARS-CoV-2 antibodies in the CVPs from recovered patients of mild symptomatic COVID-19 in North India.