Clinical Trial Details (PDF Generation Date :- Sat, 30 Sep 2023 11:28:58 GMT)

CTRI Number	CTRI/2020/07/026791 [Registered on: 25/07/2020] - **Trial Registered Prospectively**
Last Modified On	24/03/2021
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug Preventive
Study Design	Randomized, Parallel Group, Multiple Arm Trial
Public Title of Study	Statin and Aspirin in SARS-CoV-2 infection
Scientific Title of Study	A Randomised Control Trial of Statin and Aspirin as Adjuvant Therapy in Patients with SARS-CoV-2 Infection (RESIST Trial)

Secondary IDs if Any

Secondary ID	Identifier
NIL	NIL

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

Details of Principal Investigator	
Name	Dr Deepti Siddharthan
Designation	Assistant Professor
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Source of Monetary or Material Support

Source of Monetary or Material Support
> All India Institute of Medical Sciences, New Delhi, India

Primary Sponsor

Primary Sponsor Details	
Name	Dr Deepti Siddharthan
Address	Assistant Professor, Department of Cardiology, 7th Floor, CNC building, AIIMS, New Delhi-110029
Type of Sponsor	Other [Self]

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
Dr Deepti Siddharthan	All India Institute of Medical Sciences, New Delhi	Department of pulmonary medicine, COVID wards of National cancer institute ,Jhajjar, Haryana-124105, (Covid-19 hospital under AIIMS, New Delhi); Department of anaesthesia and critical care, COVID wards of JPNA Trauma centre, Ansari Nagar, New Delhi-110029(Covid-19 hospital under AIIMS, New Delhi) South DELHI	9968774019 deeptikailath@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
AIIMS Institute Ethical Committee	Approved	16/07/2020	No
AIIMS Institute Ethical Committee	Approved	06/10/2020	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
Intervention	Atorvastatin (Statin)	Tablet Atorvastatin 40mg once daily for ten days or till discharge whichever is later
Intervention	Aspirin	Tablet Aspirin 75mg once daily for ten days or till discharge whichever is later.

Comparator Agent	Conventional therapy	Conventional therapy for COVID-19 infected patients

Inclusion Criteria

Inclusion Criteria	
Age From	40.00 Year(s)
Age To	75.00 Year(s)
Gender	Both
Details	1) RT-PCR positive for SARS-CoV-19 infection, 2)Symptoms (WHO clinical improvement ordinal score 3 to 5) requiring hospital admission, 3)Consenting to participate for the trial.

Exclusion Criteria

Exclusion Criteria	
Details	1) Critical illness with WHO clinical improvement ordinal score >5, 2) Documented significant liver disease / dysfunction (AST/ALT > 240), 3) Myopathy and Rhabdomyolysis (CPK > 5x normal), 4) Allergy or intolerance to statins, 5) Allergy or intolerance to aspirin, 6) Patients taking the following medications: cyclosporine, HIV protease inhibitors, hepatitis C protease inhibitor, telaprevir, fibric acid derivatives (gemfibrozil), niacin, azole antifungals (itraconazole, ketoconazole) clarithromycin and colchicine, 7) Prior statin use (within 30 days), 8) Prior aspirin use (within 30 days), 9) History of active GI bleeding in past three months, 10)Coagulopathy, 11)Thrombocytopenia (Platelet count 12)Pregnancy, active breast-feeding, 13)Patient unable to take oral or nasogastric medications.

Method of Generating Random Sequence	Permuted block randomization, variable
Method of Concealment	Sequentially numbered, sealed, opaque envelopes
Blinding/Masking	Open Label

Primary Outcome

Outcome	Timepoints
Clinical deterioration characterised by progression to WHO clinical improvement ordinal score more than or equal to 6 (i.e., endotracheal intubation, non-invasive mechanical ventilation, pressor agents, RRT, ECMO, and mortality).	10 days or until discharge whichever is longer

Secondary Outcome

Outcome	Timepoints
Change in serum inflammatory markers (ESR, CRP, and IL-6), Trop I, CPK from time zero to 5th day of study enrollment or 7th day after symptom onset, whichever is later.	10 days or until discharge whichever is longer
Progression to ARDS	10 days or until discharge whichever is longer
Progression to shock	10 days or until discharge whichever is longer
ICU admission	10 days or until discharge whichever is longer
Length of hospital stay	10 days or until discharge whichever is longer
Length of ICU stay	10 days or until discharge whichever is longer
In-hospital mortality	10 days or until discharge whichever is longer
Safety concerns - like myalgia, myopathy, rhabdomyolysis, hepatotoxicity, bleedings (minor and major), and others (if any).	10 days or until discharge whichever is longer

Target Sample Size	**Total Sample Size=**800 **Sample Size from India=**800 **Final Enrollment numbers achieved (Total)=**900 **Final Enrollment numbers achieved (India)=**900
Phase of Trial	Phase 2/ Phase 3
Date of First Enrollment (India)	01/08/2020
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)	Completed
Publication Details	Nil
Brief Summary	The clinical manifestations and the severity of illnesses following COVID-19 infections are the result of immune dysregulations. There is an imperative need for the development of antiviral and immunomodulatory drugs that can modify the course of the disease. In this respect, an ideal adjuvant drug should be a low-cost generic medication, easily accessible in pandemics events with an established safety profile. This type of drug should aim at the host's immune response to alleviate the effects of immune dysregulation. Such anti-inflammatory and immunomodulatory agents may effectively complement the usual care in COVID-19 infection. It is with this premise that we intend to evaluate two commonly used cardioactive drugs with anti-inflammatory properties, statins and aspirin, as adjuvant therapy in COVID-19 infection. It will be a single-centre, prospective, four-arm parallel-group, open-label randomized active-control superiority trial to evaluate the safety and efficacy of atorvastatin and aspirin in reducing clinical deterioration (WHO ordinal scale more than or equal to 6) and serum inflammatory biomarkers in symptomatic (WHO ordinal scale 3-5) COVID-19 infected patients.