Clinical Trial Details (PDF Generation Date :- Thu, 22 Oct 2020 20:55:57 GMT)

CTRI Number	CTRI/2020/04/024948 [Registered on: 30/04/2020] - **Trial Registered Prospectively**
Last Modified On	30/04/2020
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug
Study Design	Randomized, Parallel Group Trial
Public Title of Study	A clinical Trial to Study the Effects of Hydroxychloroquine, Ciclesonide and Ivermectin in treatment of moderate COVID-19 illness
Scientific Title of Study	EFFICACY OF HYDROXYCHLOROQUINE, CICLESONIDE AND IVERMECTIN IN TREATMENT OF MODERATE COVID-19 ILLNESS: AN OPEN-LABEL RANDOMISED CONTROLLED STUDY

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	Anupam Prakash
Designation	Professor of Medicine
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Details Contact Person (Scientific Query)

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Source of Monetary or Material Support

Source of Monetary or Material Support
> Dr Anupam Prakash Professor, Department of Medicine Lady Hardinge Medical College New Delhi

Primary Sponsor

Primary Sponsor Details	
Name	Lady Hardinge Medical College
Address	Shaheed Bhagat Singh Marg New Delhi
Type of Sponsor	Government medical college

Details of Secondary Sponsor

Name	Address
Nil	NA

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Anupam Prakash	Department of Medicine	Room No 1014 Smt Sucheta Kriplani Hospital Lady Hardinge Medical College Shahid Bhagat Singh Marg New Delhi 110001 New Delhi DELHI	8588885305 prakashanupam@hotmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
IEC Lady Hardinge Medical College	Approved	29/04/2020	Yes

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
Patients	Other specified viral diseases

Intervention / Comparator Agent

Type	Name	Details
Intervention	Hydroxychloroquine	400 mg bid Day1 followed by 200 mg bid on Days 2 to 7
Intervention	Ciclesonide	200 mcg bid for 7 days
Intervention	Ivermectin	12 mg OD for 7 days
Comparator Agent	Standard of Care	Supportive management as per national guidelines

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	99.00 Year(s)
Gender	Both
Details	• Adult patients (?18years) suffering from Covid-19. A positive throat swab (by real time PCR) obtained from a patient suspected to be Covid-19 or from a contact (or HCW) of Covid-19 patient will be considered to be a Covid-19 case. • Presence of moderate Covid-19 disease (10) as defined by

	presence of pneumonia (clinical and radiological signs) with respiratory rate between 15 to 30/minute and/or SpO2 90%-94% on room air.

Exclusion Criteria

Exclusion Criteria	
Details	• Patients with renal or hepatic dysfunction (Serum creatinine > 1.5 mg/dL and serum transaminase levels >120 U/L) • Patients with clinical heart failure/known CAD • Known cases of neoplasms or immunodeficiency syndromes • Patients who are on chemotherapy, immunosuppressive agents, steroids or antiviral agents, or have received in the preceding 4 weeks • Pregnant and lactating patients • Uncooperative patients (in the opinion of the investigator, if it is difficult to ensure patient cooperation during the study)

Method of Generating Random Sequence	Coin toss, Lottery, toss of dice, shuffling cards etc
Method of Concealment	Not Applicable
Blinding/Masking	Not Applicable

Primary Outcome

Outcome	Timepoints
Proportion of patients having virologic cure on Day 6 in each of the groups	Day 6 of treatment initiation

Secondary Outcome

Outcome	Timepoints
o Proportion of patients having resolution of symptoms/signs on Day 7 and Day 14, in each of the groups o The individual proportion of the aforementioned rescue criteria in each of the groups. o Side-effects noted in each of the group	Day 7 and Day 14

Target Sample Size	**Total Sample Size=**120 **Sample Size from India=**120 **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	Phase 2
Date of First Enrollment (India)	15/05/2020
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)	Not Yet Recruiting
Publication Details	
Brief Summary	**Principal Investigator:** **Dr. Anupam Prakash**, Professor of Medicine, Lady Hardinge Medical College, New Delhi,

On behalf of the **LHMC Medicine COVID-19 Investigator Group**

Place of study:

Department of Medicine, Lady Hardinge Medical College and associated Hospitals, New Delhi.

Duration of study: May-October 2020

Type of study: Randomised controlled study.

The world is facing the crisis created by COVID-19, a pandemic of unassumed proportions, which does not have any known treatment yet. Several drugs are being repositioned to see their efficacy for Covid-19. This study is planned to study the efficacy of oral hydroxychloroquine, inhalational ciclesonide and oral ivermectin as treatment option in adult patients (?18 years) with moderate Covid-19 illness.

Moderate Covid-19 illness will be defined as nasopharyngeal/nasal/oropharyngeal swab positivity by PCR, along with respiratory rate of 15-30/min and SpO2 between 90-94%. Those fitting the inclusion and exclusion criteria, will be enrolled after obtaining an informed written consent, and randomized (by draw of lots) to any of the 4 arms-

(i) Group A - Hydroxychloroquine 400 mg bid oral Day 1, 200 mg bid on Day 2-7

(ii) Group B –Ciclesonide 200 mcg bid (through rotahaler) for 7 days

(iii) Group C –Ivermectin 12 mg orally OD for 7 days

(iv) Group D –Standard of care only

A sample size of 30 in each arm is proposed to be included over a period of 6 months. A focused physical examination (General appearance and behaviour including mental status, vitals and chest examination) will be performed for each subject enrolled in the study. Routine blood and radiological investigations would be performed for each subject, and an ECG just after admission, and prior to satisfactory discharge. All patients recruited will anyway receive standard of care, and the institutional/national management protocol will be followed in all other respects. Enrolled subjects will be followed up for virologic cure (primary outcome). Repeat PCR testing on fresh swab would be done on Day 6 onwards and two consecutive negative throat swabs at least 24 hours apart would constitute virologic cure (primary outcome). Any positive throat swab on Day 6 onwards, would entail repeat testing after 48 hours. Trial drug would be continued in each group (A, B and C) would be continued for a period of 7 days, though follow-up will be for a period of virologic cure, to a maximum of 14 days. Trial drug would be withdrawn if they deteriorate to severe Covid-19 illness or

disseminated intravascular coagulation (DIC) or shock. However, they will be included for the purpose of analysis.

Secondary outcomes include (1) Proportion of patients having resolution of symptoms/signs on Day 7 and Day 14 in each of the groups, (ii) Subjects deteriorating in to severe Covid-19 or developing DIC/shock, (iii) Side-effects observed in each of the group.

The comparative analysis will be performed using ANOVA testing, and the reporting would be done as per CONSORT guidelines.