Clinical Trial Details (PDF Generation Date :- Thu, 22 Oct 2020 20:29:55 GMT)

CTRI Number	CTRI/2020/05/025242 [Registered on: 19/05/2020] - **Trial Registered Prospectively**
Last Modified On	18/05/2020
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug
Study Design	Other
Public Title of Study	Hydroxychloroquine of pharmacokinetics in healthcare workers
Scientific Title of Study	Population pharmacokinetics of hydroxychloroquine sulphate in healthcare workers given for prophylaxis against Corona Virus Disease 2019 (COVID 19) pandemic in India

Secondary IDs if Any

Secondary ID	Identifier
83341	Protocol Number

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

Details of Principal Investigator	
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Designation	Professor Additional
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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
> Indian Council of Medical Research

Primary Sponsor

Primary Sponsor Details	
Name	Indian Council of Medical Research
Address	V. Ramalingaswami Bhawan P O Box No 4911 Ansari Nagar New Delhi 110029 India
Type of Sponsor	Government funding agency

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 Nihtya Gogtay	Dept of Clinical Pharmacology	1st floor Seth GSMC and KEM Hospital Parel Mumbai Mumbai MAHARASHTRA	02224133767 njgogtay@hotmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institutional Ethics Committee	Approved	04/05/2020	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	Healthcare workers

Intervention / Comparator Agent

Type	Name	Details
Intervention	Hydroxychloroquine sulphate	Oral tablet 400 mg twice a day on Day 1, followed by 400 mg once weekly for next 7 weeks to be taken with meals
Comparator Agent	Not applicable	Single arm study

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	65.00 Year(s)
Gender	Both
Details	Asymptomatic Health Care workers (HCWs) of any gender and conditions as follows: age 18 -65 years (HCW who are actively on duty and not any who have retired) on prophylaxis with HCQ against COVID-19 infection – Group 1 without comorbiditie age 18 -65 years (HCW who are actively on duty and not any who have retired) who are to be initiated on prophylaxis – Group 2 without comorbidities age 18 -65 years (HCW who are actively on duty and not any who have retired) on prophylaxis with HCQ against COVID-19 infection with comorbidities (HT, Diabetes) – Group3 age 18 -65 years (HCW who are actively on duty and not any who have retired) who are to be initiated on prophylaxis – Group 2 with

	comorbidities (HT, Diabetes)

Exclusion Criteria

Exclusion Criteria	
Details	Health care workers who show symptoms suggestive of COVID-19 or are positive for COVID-19 Women of child bearing potential who are not willing for adequate contraception during the time of blood collection / who were not practicing adequate contraception in the last 28 days Women who are pregnant or breast feeding Participants who are not determined to be fit by the investigator Participants who are prescribed HCQ for any other indication / history of taking HCQ in the last one year

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

Primary Outcome

Outcome	Timepoints
The modelling will help assess which of the variables including the presence of comorbidities (if any) would have the greatest impact on the drug concentrations in an Indian population. It would also help us understand if COVID-19 infection alters the pharmacokinetics of HCQ.	2-8 weeks

Secondary Outcome

Outcome	Timepoints
It would also help us understand the concentrations of HCQ in lung fluid using PBPK modelling	2-8 weeks

Target Sample Size	**Total Sample Size=**400 **Sample Size from India=**400 **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)	25/05/2020
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**1 **Months=**0 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Not Yet Recruiting
Publication Details	After data analysis , study will publish.
Brief Summary	Corona Virus Disease 2019 (COVID-19) had its origin in Wuhan, China in December 2019 and was subsequently found to have been caused by a novel corona virus named severe acute respiratory syndrome corona virus 2 (SARS-CoV-2). It later spread to many nations and the World Health Organisation declared it a pandemic on 12 March 2020. As the health crisis was looming all over the world with thousands reported to have

contracted the disease, some of whom died, the search for various treatment options took great priority. Accordingly repurposing of old and approved drugs such as chloroquine, hydroxychloroquine (HCQ), azithromycin, metformin, angiotensin receptor inhibitors such as sartans, or statins such as simvastatin were considered to be useful for the treatment of this disease. [4] Of these, hydroxychloroquine has garnered much attention as a potential prophylactic / treatment option for COVID-19.

With mounting evidence on the possible beneficial effect of HCQ in the prevention and treatment of COVID-19, there is limited information on the pop PK of HCQ in an Indian setting when administered for the prophylaxis of COVID-19. Thus, the current study gains greater importance given the current pandemic with COVID-19.