RUTGERS
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CINJ # 002011

Randomized Comparison of Combination Azithromycin and Hydroxychloroquine vs. Hydroxychloroquine Alone for the Treatment of Confirmed COVID-19

Patient Study Number:	**Hispanic or Latino?** Yes or No
Name: *Medical Record Number:* *DOB:*	**Race** (Must circle AT LEAST one choice): American Indian/Alaskan Native Asian Black/African American White Native Hawaiian/other Pacific Islander

INCLUSION CRITERIA		***Circle Y=yes N=No***	
1.	Patients with proven SARS-CoV-2 infection by qPCR assay with symptoms consistent with COVID-19	Y	N
2.	Ability to measure and quantify viral load by quantitative PCR	Y	N
3.	Age 18-89	Y	N
4.	Ability to swallow oral medications	Y	N
5.	Patients must read, understand and sign IRB approved informed consent	Y	N
IF THE ANSWER TO ANY CRITERIA ABOVE IS "NO", <u>DO NOT ENROLL THE PATIENT</u>			

EXCLUSION CRITERIA		***Circle Y=yes N=No***	
1.	Pregnancy or women who are breast feeding.	Y	N
2.	Two consecutive negative assays for SARS-CoV-2 infection	Y	N

3.	Patients that lack decision-making capacity (will not be approached to participate in this study)	Y	N
4.	Inability to tolerate oral medications.	Y	N
5.	Allergy or prior adverse reaction to either azithromycin or hydroxychloroquine sulfate.	Y	N
6.	QTc interval $\geq$ 470 mSEC	Y	N
7.	History of ongoing ventricular cardiac dysrhythmias of grade 2 as described by NCI CTCAE 5.0 criteria	Y	N
8.	History of serious ventricular arrhythmia (VT or VF > 3 beats in a row).	Y	N
IF THE ANSWER TO THE CRITERIA ABOVE IS "YES", <u>DO NOT ENROLL THE PATIENT</u>			

The above protocol and informed consent was explained to the patient (and family members/significant others) including, but not limited to, the risks, benefits, treatment plan, contact numbers, etc. All questions have been answered to the patient's (and family members/significant others) satisfaction. A copy of the signed informed consent was provided.

Completed by: _____Date: _____

MD Verification: _____Date: _____

Part 2 – Cancer Institute USE ONLY

PRE-SCREENING REQUIREMENTS (Evaluations completed on day of screening)		
Date Done	**REQUIREMENTS:**	**Scheduled for:**
	Informed Consent Signed	
	Baseline History and Physical, Vital Signs	
	Demographics	
	Eligibility Review	
	Concomitant Medications	
	Baseline COVID Signs and Symptoms Questionnaire	
	12-lead Electrocardiogram	
	Labs: CBCD, Ferritin, D-Dimer, LDH, CRP and Troponin	
	Serum Pregnancy test (if applicable)	
	Research Specimens Collected: • 3 oropharyngeal swabs • Saliva swab • Research blood draw	
	Severity Assessment Criteria • Temp >100.5°F (1 point) • Fatigue (1 point) • Cough (1 point) • Shortness of breath (1 point) • Heart rate >90 BPM (2 points) • Respiratory rate > 14 breathes/min (2 points) • Pulse Ox < 94% on room air (3 points) • Blood pressure < 90/60 (3 points) Score: Mild/Moderate = 0-7 points Severe = 8-15 points Score: _____	
	Document location of patient: • Inpatient _____ • Outpatient _____	
	Education provided to patient on how to complete pill diary and temperature log.	

Completed By RNC: _____ Date: _____

Created by: T. Saunders on 3/27/20
QA'd by: S. Datta on [4-7-20], protocol version 3.0 4-7-20