SYNOPSIS OF THE STUDY

Protocol title	Phase IIb open randomized clinical trial to evaluate the efficacy and safety of chloroquine chemoprophylaxis in healthcare professionals at high risk for SARS-CoV-2 infection
No. Protocol of the Promoter.:	
Development phase:	Phase IIb
Prosecutor:	Oswaldo Cruz Foundation (FioCruz)
Funders:	FINEP and FAPEMIG
Responsible doctor's sponsor and coordinator	Dr. Israel Molina
Manufacturer of the Drug	Farmanguinhos
Research team	Unai Tupinambas (UFMG), Mateus Rodrigues Westin (HC- UFMG), , Pablo Martínez de Salazar, Leonardo Pinto, Glauco Nardotto, Pedro Augusto Alves, Mauro Teixeira, Flávio da Fonseca, , Jacqueline Oliveira Ferreira, FernandoBotoni, Chirley Madureira Rodrigues.
Study Centers:	Hospital Das Clínicas/Ebserh Branch of the Federal University of Minas Gerais (HC/EBSERH-UFMG) UFMG, , Hospital Eduardo de Menezes, Central-South Emergency Care Unit of the City of Belo Horizonte, Hospital JuliaKubitschek.
Study Objectives	**Main objective** To evaluate the efficacy of a weekly dose of prophylactic Chloroquine (CK) in health professionals who provide direct care to patients with suspected and/or infected with SARS-CoV-2 in health units in Belo Horizonte, compared to a control cohort, after 4 weeks of follow-up. **SecondaryGoal s s**

	• To evaluate the efficacy of a weekly dose of CK in the prevention of SARS-CoV-2 infection in health professionals who provide direct care to patients with suspected and/or infected with SARS-CoV-2 in health units in Belo Horizonte, compared to a control cohort, at the end of 12 weeks of follow-up. • To evaluate the weekly dose safety profile of CK as prophylaxis of SARS-CoV-2 infection based on clinical events detected and/or self-reported over 12 weeks of follow-up; • Evaluate the daily viral load in participants presenting COVID-19 confirmed by PCR (subgroup of 50 in each arm). • To evaluate the number of participants with asymptomatic SARS-CoV-2 infections, through IgM and/or IgG seroconversion, at the end of 12 weeks of follow-up. • Evaluate the acceptability and adherence of the intervention over 12 weeks of follow-up. • Evaluation of PK profiles in a subpopulation of the study
Study Design	Open-label, randomized, multicenter, clinical study controlled by a group that will receive standard prevention guidance.
Medicinal product under evaluation:	Participants who meet the inclusion criteria will be randomized into 2 arms: • Chloroquine 600 mg / week for 12 weeks + standard care; • Standard care (which include guidelines for preventing SARS-CoV-2 infection and use of the respective recommended PPE). In each group will be included 500 participants. Chloroquine is a medicine widely used in prophylactic antipaludic therapy. Chloroquine is produced by Farmanguinhos.
Target study population	Healthp rofissional patients assisting patients with suspected and/or infected SARS-CoV-2
Eligibility criteria	**Eligibility criteria** The study is designed for the participation of adults (>18 years), health professionals who provide direct assistance to patients hospitalized with suspected and/or infected by SARS-CoV-2. All inclusion and exclusion criteria must be met to ensure eligibility: **INCLUSION CRITERIA** A participant must meet all of the following criteria: 1) Health professionals who provide care to patients with suspected or confirmation of SARS-CoV-2 infection who work in the ICU/ICU, emergency rooms or wards in health units in Belo Horizonte. 2) Be able to provide proof of identity, personal and professional, satisfactory to the physician responsible for the inclusion process;

	3) Be willing to complete the process of free and informed consent and able to do so; 4) Being willingto adhere to the studyprotocol. 5) Age 18 years or older **CRITERIONS OF EXCLUSION** A participant will be excluded if they present one or more of the following conditions: • 1) History of known allergy to the study drug; • 2) Flu-like signs and symptoms at the time of inclusion; • 3) Known pregnancy (no pregnancy test required) • 4) Previous or current history of retinopathy; • 5) Electrocardiogram on the day of screening with increased QTc interval: >470ms for Men and > 480 for women) OR Tisdale score >7 (see Annex 15.1). • 6) Weight <40 kg; • 7) Any immunosuppressive condition or hematological disease. • 8) To present a clinical, psychiatric or social condition that, according to the researcher's assessment, may prevent adherence to the study protocol;
Main variables	*Efficacy variables:* • Incidence of COVID-19 cases confirmed by PCR at the end of 4, 8 and 12 weeks. *Security variables* • Incidence and severity of adverse events over the 12 weeks of follow-up. • Treatment interruptions.
Duration ofthe Study	The duration of the follow-up of the study will be 12 weeks, regardless of the arm that the participant is allocated. The inclusion period is expected to be completed and2 and 4 weeks.