SYNOPSIS OF THE STUDY

<table>
<thead>
<tr>
<th>Protocol title</th>
<th>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</th>
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<tbody>
<tr>
<td>No. Protocol of the Promoter:</td>
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<td>Development phase:</td>
<td>Phase IIb</td>
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<tr>
<td>Prosecutor:</td>
<td>Oswaldo Cruz Foundation (FioCruz)</td>
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<tr>
<td>Funders:</td>
<td>FINEP and FAPEMIG</td>
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<tr>
<td>Responsible doctor's sponsor and coordinator</td>
<td>Dr. Israel Molina</td>
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<tr>
<td>Manufacturer of the Drug</td>
<td>Farmanguinhos</td>
</tr>
<tr>
<td>Research team</td>
<td>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, Fernando Botoni, Chirley Madureira Rodrigues.</td>
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<tr>
<td>Study Centers:</td>
<td>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.</td>
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| 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.  

 **Secondary Goals**  

- 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**

Health professionals assisting patients with suspected and/or infected SARS-CoV-2

**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 willing to adhere to the study protocol.
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;

<table>
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<tr>
<th>Main variables</th>
<th>Efficacy variables:</th>
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<td></td>
<td>Incidence of COVID-19 cases confirmed by PCR at the end of 4, 8 and 12 weeks.</td>
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</table>

**Security variables**

- Incidence and severity of adverse events over the 12 weeks of follow-up.
- Treatment interruptions.

**Duration of the 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 and 2 and 4 weeks.