ETHICS COMMITTEE: Informed Consent

STUDY TITLE: Safety and Efficacy Study of oral Ivermectin in the Prophylaxis of COVID-19 Disease in Individuals Post-exposure to COVID-19 by Close Contact or Epidemiological Nexus.

The emergency of COVID-19 requires the urgent development of strategies to avoid the impact of the disease on our population, the saturation of the health system and to allow us to carry out adequate treatments to reduce the mortality of the disease. Upper respiratory tract infection has a major impact on the transmission and pathogenesis of SARSCoV2. The role of saliva and salivary glands in the first stage of viral infection is becoming increasingly well known. Any measure located in the oral cavity to reduce viral load will reduce the level of contagion in the social environment of each person. Given that the viral RNA detection diagnostic test is not immediate and that contagion control is essential during the first days of the development of the disease. This treatment, even in suspected cases of COVID-19, contributes to the control of contagion in the first phase of the infection, even when there are no symptoms of the disease. We propose an efficacy and safety study to evaluate the use of oral Ivermectin in the prophylaxis of COVID-19 disease in Individuals Post-exposure to COVID-19, whether by close contact or epidemiological link.

As you are a person at risk, you are invited to participate in this study where it will be evaluated by monitoring a medication already approved by the Institute of Regulation: National Administration of Medicines, Food and Medical Technology (ANMAT) of Argentina. However, the ANMAT approved the use of IVERMECTIN in humans but for other therapeutic purposes; here the use of them is proposed outside the prospectus or under treatment of a new indication such as prophylaxis of infection by coronavirus.

Objective: Evaluate the effect of oral Ivermectin, on the appearance and eventual progression of COVID-19 disease, for prophylaxis of COVID-19 infection exposed to it because it is an epidemiological link or close contact. As it is a research protocol, your participation will be voluntary and there will be a total protection of the confidentiality of your data, and you can refuse or not to participate in it, as well as you can withdraw at the time you want, your decision being not communicated in any way to any person.

Likewise, you will be given the contact information: E-mail address and phone number of the team of researchers, so you can inform the team if there is any undesired effect.

Intervention: It will be carried out in a first visit to a health center designated by the SIPROSA system. Covid-19 care center, it may also be your home or another public institution that adheres to the treatment, the monitor center will be the Medical Executive Secretary of SIPROSA. Ivermectin will be given to me to take 6 tablets once a week (if I have a weight of 70

kg or more, one more tablet will be added). This treatment will have a single repetition a week. It is recommended that I take them with food, that is, with lunch.

I am informed that if I present symptoms for Coronavirus infection, I will have a nasopharyngeal swab for diagnosis of COVID-19 by RT-PCR. If my sample tests positive for coronavirus, prophylaxis treatment will be suspended no matter what stage it is in. This way you will be able to receive the care proposed by the health team that will be designated to attend to the positive cases and that do not belong to the investigation team of this studio. Once prophylaxis is suspended, the study follow-up phase begins for 21 days.

Total Duration of the Study: 14 days: Intervention Period (7 days) and post-intervention follow-up (7 days): with the Initial Visit for questioning about my background, signing of this consent and taking a sample for PCR, Visit 1 for control and dispensing of the first dose. A telephone communication on day 4 and 2 more visits: a visit on day 7 for clinical control and dispensing of the second dose and another visit on day 14 where I will have a clinical control and PCR.

Characteristics of Ivermectin: Ivermectin is a drug in use for a long time in the antiparasitic treatment (vermicide) both in animals and in man. Ivermectin is not approved for use in COVID-19 at this time.

Although the side effects of ivermectin are mild, very infrequent and all are temporary. These effects are due to the toxic substances released after the vermicidal action. These effects revert after stopping the drug. Likewise, the following hypersensitivity reactions could occur, which are pruritus, conjunctivitis, arthralgia, myalgia (includes abdominal myalgia), fever, edema, nausea, vomiting, diarrhea, lymphadenopathy, orthostatic hypotension, tachycardia, asthenia, rash and headaches . These symptoms are rarely severe. Ophthalmic side effects are rare after treatment, but an abnormal sensation in the eyes, papilledema, anterior uveitis, conjunctivitis, limbites, keratitis, chorioretinitis or choroiditis, that can occur because of a condition of themselves, can be found occasionally during treatment. They are rarely severe and generally disappear without the help of corticosteroids. Symptoms of drowsiness and non-specific transient ECG changes were reported. Sometimes transient eosinophilia may appear. As ivermectin is contraindicated in pregnancy and lactation. To rule out the probability of pregnancy in women of childbearing age, a pregnancy test will be performed before enrolling the patient in the study. Sometimes transient eosinophilia may appear. As ivermectin is contraindicated in pregnancy and lactation. To rule out the probability of pregnancy in women of childbearing age, a pregnancy test will be performed before enrolling the patient in the study. Sometimes transient eosinophilia may appear. As ivermectin is contraindicated in pregnancy and lactation. To rule out the probability of pregnancy in women of childbearing age, a pregnancy test will be performed before enrolling the patient in the study.

There is a possibility that prophylactic treatment with ivermectin may not have a beneficial effect against coronavirus infection. This may provide interesting data along with other investigations to be able to use it after the analysis of the collected data.

Several Research studies are in progress, but they need more time to get results. The Ministry of Health of Tucumán has evaluated the different drugs that are being tested in studies that are underway and others that have been completed and, after the opinion of research experts, considers that the use of ivermectin as a prophylaxis to avoid infection by coronavirus for people exposed to contact either by close contact or by epidemiological link with suspected or positive patients for coronavirus would be an alternative.

Your participation in the study is voluntary, and if you agree to participate, you can still withdraw from the study at any time. This will not affect your care or your working conditions. All your data will be confidential and only the researchers will know your identity.

There is no cost to participate and you will not be paid to participate.

Data of the study researcher to be able to communicate
Dra: Marcela Dive Mohamed who can be contacted at any time during the study
Cell phone number 381 6 136 900 or
Medical Executive Secretary Siprosa semsiprosa@gmail.com -tel.- 0381 4 526 111- internal 10

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I have been informed that I can participate in this research study to test the effect of ivermectin as a preventive treatment to avoid coronavirus infection.

I understand that the drug ivermectin is currently approved by the National Administration of Medicines, Food and Medical Technology (ANMAT) of Argentina, but only for use as a vermicide and that it is not yet approved for use in prevention or infection by Coronavirus.

The Ministry of Public Health of Tucumán and the researchers responsible for this study may suspend the carrying out of this study for different reasons at any stage of its development.

I give my consent to receive the prophylactic treatment with ivermectin proposed by the researchers of the Ministry of Health of the Province of Tucumán for my Coronavirus COVID-19 infection.

Patient Name_____

DNI_____

Date_____

Name of Witness (if applicable) _____

DNI_____

Date_____

Investigator's Name_____

DNI_____

Date_____

The Health Research Directorate will be in charge of Project Management.

Health Research Directorate - SIPROSA mail: dir_investigacion@msptucuman.gov.ar