PATIENT INFORMATION AND INFORMED CONSENT FORM

Study Title: RESEARCH PROTOCOL FOR REPROPOSING *OF IVERMECTIN IN THE TREATMENT OF MILD STAGE PATIENTS WITH CORONAVIRUS DISEASE (COVID-19) in Primary Health Care Center*

Principal Investigator's Name: Prof. Dra. Rossana Chahla

Healthcare Center / Unit where the Protocol will be carried out: ……

24-hour contact telephone number: …… ...

Introduction:

The COVID-19 coronavirus pandemic has produced a humanitarian catastrophe that puts the lives of many patients around the world at risk. Faced with this unprecedented situation, various treatments have begun to be evaluated around the world with the aim of solving this emergency. The most important complication of this infection is respiratory failure, which is the main cause of mortality. The accumulated evidence suggests that hospitalized patients with COVID-19 could present a picture of increased inflammation that would be responsible for these complications.

This research protocol to which you are being invited to participate consists of a research study that will evaluate the effect of Ivermectin treatment in early stages of covid-19 disease (mild outpatients).

Before signing this informed consent form please take time to read it carefully (or have it read to you) to fully understand the following information. You can ask the study doctor or members of his team any questions you may have about the study or your rights.

You are completely free to accept or decline to participate in this study.

Objectives of the study:

The objective of the study is to determine if the use of Ivermectin, administered in 4 doses of 24 mg (4 tablets orally) every 7 days for 4 weeks, in outpatients with Sars Cov2 infection in which they are in a mild stage, can reduce the viral load and help together or in extension to other treatments to which you are receiving, stop and / or reverse the progression to developing moderate or severe stages of Covid 19 disease. The objective is to apply this study to patients whoare treated in a health care center that participates in this protocol and that belongs to the Provincial Health System of the Province of Tucumán.

Study procedures:

After completing this informed consent process and, if you meet the criteria to be chosen, you will receive 1 dose of 24 mg of ivermectin consisting of 4 tablets of 6 mg each to be repeated every 7 days, for 4 weeks. You must have 2 (two) hours of fasting before and 2 (two) hours of fasting (without food intake) after taking the medicine.

The medical team, if you agree to take Invermectin, will add it to the treatment that you have been carrying out, understanding that he is the professional responsible for decisions about your care and safety.

Pregnancy and breastfeeding:

If you plan to become pregnant during the study, do not participate. Pregnant or lactating women were excluded from the study.

Biochemical and hematological parameters in blood.

This study does not foresee biochemical analysis nor specific hematological. Your doctor will order the tests that are necessary for the clinical follow-up of your disease.

Voluntary participation:

Your participation in this study is free and voluntary. You can refuse to participate. If you do not wish to participate, the care at the Center or Assistance Unit will not be affected in any way, you will not be punished or lose the benefits to which you are entitled.

Any new information that may affect your health or influence your willingness to participate in the study will be informed immediately.

If you decide not to be part of the study, you will receive care according to standard practice. You do not have to be in the study to receive care for your condition.

Benefits:

This investigational treatment may not be more beneficial or add more benefits to the usual treatment for COVID-19. The data obtained from this study may help other patients with the same condition. However, if the treatment is effective, you will benefit and help us with scientific knowledge on this subject.

Confidentiality and protection of personal data:

During your participation in this study, the medical team will review your medical history and record your personal and medical information to conduct the study. All information collected will be kept strictly confidential. To protect your identity, your personal information will be identified only with a code that will be assigned to replace your name.

Any transfer of this information will be carried out in accordance with Law 25,326 that protects the handling of personal data and the transfer of personal information.

"The National Directorate for the Protection of Personal Data, dependent on the Agency for Access to Public Information, a control body of law 25,326, has the power to address queries, complaints or claims that are filed in relation to any question regarding the protection of personal data For this purpose, you may contact: Avenida Presidente General Julio Argentino Roca 710 - CABA 2 ° piso, www.argentina.gob.ar/aaip. "

It is possible that representatives of the ethics committee, provincial regulatory authorities, have access to your data from this research and your medical history.

Compensation and costs:

You will not receive any payment for your participation in this study. Study medication and related procedures will be at no cost to you.

Injuries and damages:

"By signing this informed consent you do not waive the rights you have in accordance with the Civil and Commercial Code and Argentine laws on civil liability for damages and that may correspond to you in the event that any damage occurs as a result of your participation in this study. "

Contacts:

If you have questions related to this study, in case of any damage, or if you wish to withdraw from the study, you can contact at any time with: Principal Investigator: Dra. Rossana E. Chahla - Mail: rchahla@yahoo.com.ar

This research study has been reviewed by the **Research Ethics Committee (CEI) of the SI.PRO Research Directorate. SA.**This committee is in charge of ensuring that the rights of human subjects are protected.

For information regarding your rights as a participant in a research study, you should contact the **SIPROSA Health Research Directorate Director: Dra. Maria Peral de Bruno. Virgen de la Merced 189 - First floor. San Miguel de Tucumán. Mail:**dir_investigacion@msptucuman.gov.ar

INFORMED CONSENT FORM

- I have read (or had read to me) the information sheet for the aforementioned study and have had an opportunity to ask questions. All my questions have been answered in a way that I understand.
- I have received the name of the contact person if I have any questions
- I understand that my participation is voluntary and that I am free to withdraw my consent to participate in this study at any time without penalty or loss of benefits to which I am entitled. I know enough about the purpose, methods, risks, and benefits of the study to decide that I will participate in it.
- I consent in which the medical team collects and processes information, including information about my health. I consent to my encrypted information being processed by the sponsor. If I decide to withdraw from the study, I agree that the information collected about me, until the moment I withdraw, will continue to be processed.
- My identity will never be disclosed except as required by law and any information collected will be kept confidential. I accept that my medical history and any other personal data generated during the study may be reviewed by representatives of the ethics committee and competent provincial regulatory authorities. I agree not to restrict the use of the study results by the sponsor.
- By signing this form I agree freely and voluntarily to participate in this study. I understand the risks of possible side effects associated with the study drugs. Once signed and dated, I will receive one of two signed and dated copies of this consent and information form.

Participant

Signature of participant name	and surname of participant	ID Number	Date

By signing this informed consent, you do not waive the rights you have in accordance with the Civil and Commercial Code and Argentine laws on civil liability for damages and that may correspond to you in the event that any damage occurs as a result of your participation. in this studio.

INVESTIGATOR

I have explained the terms of this patient information and informed consent form to the above-named participant, have answered all of the questions posed and apparently understood by the participant.

Signature of Investigator Name	and surname of Researcher DNI	Date