INSTITUTO MEXICANO DEL SEGURO SOCIAL
SEGURIDAD Y SOLIDARIDAD SOCIAL

MEXICAN SOCIAL SECURITY INSTITUTE
EDUCATION, RESEARCH UNIT
AND HEALTH POLICIES
COORDINATION OF HEALTH RESEARCH

Informed consent letter for participation in research protocols (adults)

Study Name:	PRONOSTIC MODIFICATION IN PATIENTS WITH COVID-19 UNDER EARLY INTERVENTION TREATMENT IN U.M.F 13 AND U.M.F 20
External Sponsor (if applicable):	DOESN'T APPLY
Place and date:	Family Medicine Unit No. 20, Vallejo Causeway 675 cabbage. Magdalena de las Salinas México D.F. Delegation Gustavo. A.Madero and Family Medicine Unit No. 13, Villa Azcapotzalco between Hidalgo and Aztecs, Delegation Azcapotzalco. December 11, 2020
Institutional registration number:	R-2020-785-176
Justification and objective of the study:	Coronavirus, known as SARS-CoV2,is a serious disease in humans and to date there is no approved and distributed treatment for its use. In recent months there have been many initiatives toassessthe capacity of various medicines against SARS-CoV 2. Drugs such as Ivermectin are known for its antiparasitic activity, however it has been evaluated in recent years for its activity in laboratory studies against various viruses such as yellow fever, among others. This medicinal product has been granted in patients with COVID-19showing considerable benefit however it is recommended to perform research protocols with greater confidence in order to consider it for administration. Similarly, the well-known antibiotic Azithromycin has shown benefits in COVID-19 patients. The drug with name Rivaroxaban,is ananticoagulant that also has anti-inflammatory action as well when administered in patient COVID-19 has reported a decrease in mortality in patientswith C OVID-19, however it is recommended to perform research protocols to give greater confidence in its administration. The objective of the study is to evaluate the percentage of patients diagnosed with COVID-19 who modify their clinical evolution under a comparative treatment of early intervention in rightholders of the U.M.F 13 and U.M.F 20 of the I.M.S.S., during the period December 2020- February 2021.
Procedures:	If you participate in this study after the positive COVID19 test, you will betold to take medicine s according to thegroups youe handleandwill be according to those prescribed by the researchdoctor, it could be **Grupo A with** taking the following medicines: Paracetamol 500 mg orally 1 tablet every 8 hrs for 3 days in case of fever equal to or greater than 38.3oC, Azithromycin 500 mg tablets will take 1 tablet single dose on the first day and then half a tablet (250 mg) orally every 24 for 4 days, Ivermectin tablets of 200mcg which will be calculated according to your pesoand dosage,will be every 24 hrs for 4 days and Rivaroxaban tablets of 10 mg will take 1 every 24 hrs for 10 days. If you have the **Grupo B** takea Paracetamol 500 mg via oral 1 tablet every 8 hrs for 3 days in case of fever equal to or greater than 38.3oC, Azithromycin 500 mg tablets will take 1 tablet single dose on the first day and posteriormente half tablet orally every 24 for 4 days and Rivaroxaban tablets of 10 mg will take 1 every 24 hrs for 10days. Also during the taking of medicines and subsequently until you complete 14 days you will be madea videocall daily at a time of 10 am to 14 pm, including Saturday and Sunday to know how your clinical symptoms are, adverse reactions to drugs related to COVID19, duration of this video callwill beapproximately 15 minutes through your cell phone using the video call via WhatsApp. During the first day of your participation in the protocol you will be informed to attend IMSS Zone General Hospital No.48 at 8:30 am, in the laboratory area for the extraction of 5 milliliters of blood and perform hematicbiometrics,C-reactive protein, d-r-D, ferritin, protrombintime, thromboplastin time and lactic dehydrogenase.

Possible risks and discomfort:	By participating in this study and taking medications for 14 days you may have allergy to some of these medications or some other symptoms such as diarrhea, nausea, vomiting, disorientation, dizziness, asthenia, equations, petechiae, vertigo, ringing of ears, intestinal bleeding, angioedema, palpitations, hives, chest pain. Upon surveillance by the video callyou can reportany inconvenience and be able to give the handling or indication for second level shipping.
Possible benefits you will receive when participating in the study:	No financial, service or drug benefits will be received outside of those indicated when you participate in this study. By obtaining adequate clinical symptom improvement results and avoiding complications of patients with COVID19, the benefits will befor the entire population who in the future suffer from thisdisease, the drug may be granted initially in our family medicine units.
Information on treatment results and alternatives:	If during your participation there are also new reports of medicines better than those indicated are reported or when the request to suspend any for serious effects will also be given the indication of suspension and nomeans to avoid anydamage.
Participation or withdrawal:	Participation in this study is voluntarily subsequent in providing procedural information, possible risks and discomfort. If you decide to participate by signing this informed consent and subsequently decide to withdraw you can do so at the time you decide without any impact on the services you receive within the IMSS or any retaliation. After the withdrawal in case you decide all the data provided and video call will be deleted.
Privacy and confidentiality:	The data provided and when the results of this study are published, no information will be given that could reveal your identity. Your identity will be protected and hidden. In case you request your results it will only be done in a personalized way to protect your identity we will assign you a folio number or code and with it you can request your results by appointment.

Consent Statement:

After I have read and explained all my doubts about this study:

☐ I do not agree to participate in the study.

☐ If I agree to participate in the study

In case of doubts or clarifications related to the study, please contact:

Investigator or Responsible Investigator:	Dr. Gilberto Cruz Arteaga . Clinical Coordinator of Education and Research in Health Enrollment 99351417, Enrollment Family Medicine Unit 20. Vallejo 675 Col. Nueva Vallejo, C.P. 07750 Mayor Gustavo A. Madero.,CDMX Tel 53 33 11 00 Ext. 15320 and 15368. E-mail: gilberto.cruz@imss.gob.mx Dr. Alma Italia Guerrero Martínez, Clinical Coordinator of Education and Research in Health Enrollment 99368649 Adscription Family Medicine Unit 13-HGO Villa Azcapotzalco between Hidalgo and Aztecs Del. Azcapotzalco C.P. 02000 CDMX. Tel 55612700 Ext. 21315 E-mail: Italia.guerrero@imss.gob.mx
Collaborators:	Dr. José Antonio Zamudio González, Holder of the Administrative Operation Body Deconcentrada Norte DF. Adscription Delegacion Norte Distrito Federal Av. Instituto Politécnico Nacional No. 5421 Col. Magdalena de las Salinas, Del. Gam. C.P. 07760. Tel (55) 5586-2479, (55) 5754-5771, (55) 5747-3500 Ext. 25001 E-mail: jose.zamudio@imss.gob.mx Dr. Jorge Luis Zendejas Villanueva. Holder of the Head of Medical Services Services. Admission Delegacion Norte Distrito Federal Av. National Polytechnic Institute No. 5421 Building 3 Floor 1. Col. Magdalena de las Salinas, Del. Gam. C.P. 07760. Tel 51190990, 57473500 Ext. 52082 E-mail: jorge.zendejas@imss.gob.mx Dr. Elizabeth López Rojas. Planning Coordinator and Institutional Liaison. Registration:98155617. Admission Delegacion Norte Distrito Federal Av. National Polytechnic Institute No. 5421 Building 3 Floor 1. Col. Magdalena de las Salinas, Del. Gam. C.P. 07760. Tel. (55) 5747-3500 Ext. 25193 E-mail: elizabeth.lopez@imss.gob.mx

In case of doubts or clarifications about your rights as a participant you can contact: Local Committee of Ethics of Health Research of the ICU of the ICS of the IMSS: Avenida Cuauhtémoc 330 4th floor Block "B" of the Congress Unit, Colonia Doctors. Mexico City, CP 06720. Phone (55) 56 27 69 00 extension 21230, email: comiteeticainv.imss@gmail.com

Name and signature of the participant

Name and signature of who gets consent

Witness 1

Witness 2

Name, address, relationship and signature

Name, address, relationship and signature

Key: 2810-009-013

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INVITATION TO PARTICIPATE IN THE PROTOCOL

Ihereby extend to you a cordial invitation to participate in this protocol entitled "PRONOSTIC MODIFICATION IN PATIENTS WITH COVID-19 UNDER AN EARLY INTERVENTION TREATMENT IN THE U.M.F 13 AND U.M.F 20", that you intend that if you have positive COVID19 testing during the onset of the disease, you will be given the opportunity to receive pharmacological treatment for COVID-19, consideringfor your clinical follow-up of the disease the use of video callvia WhatsApp for 14days, by medicalpersonnel, granting you the benefit if this protocol successfully results in an improvement of symptoms and signs of COVID-19 disease and thus avoid complications thereof; in the same way you are granted these benefits for the whole population that in the future suffers from this disease. On the other hand you are free to leave treatment for any reason you consider disagreeing to remain in protocol.