Supplement 01

IvermecPrev-Brazil: Protocol for a double-blind, randomised controlled trial using ivermectin for COVID-19 prophylaxis in asymptomatic adults without prior immunity to SARS-CoV-2 during the 2020-2022 pandemic in Brazil

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Date of study enrolment	/ /
NAME OF PERSON filling out form:	
Participant name*	
SUS card number	
CPF number	
Birth date	/ /
Institution name	FMS - Mamanguape Municipal Health Fund

1a. DEMOGRAPHICS

Sex	○	Male			○	Female									
Birth date			/ /												
Age		years													
Health worker?			○	YES		Emergency		Ward			Other	○	NO		
Job title															
HAD COVID-19 ?				○	YES		○	NO							
TOOK A RAPID TEST ?				○	YES		○	NO							
WAS THE RESULT POSITIVE ?				○	YES		○	NO							

1b. INCLUSION CRITERIA

Age	»	Age ≥ 18 years	○	YES		○	NO
CLINICAL: presence of one or more of these signs or symptoms of disease in the **last two weeks**	»	Self-reported or measured fever of ≥ 38 °C	○	YES		○	NO
	»	Cough	○	YES		○	NO
	»	Dyspnea (shortness of breath) OR Tachypnea*	○	YES		○	NO
	»	Clinical suspicion despite not meeting the above criteria (use the list below)	○	YES		○	NO
	»	Headache	○	YES		○	NO
	»	Nasal discharge	○	YES		○	NO
	»	Sore throat	○	YES		○	NO
	»	Change in smell	○	YES		○	NO
	»	Change in taste	○	YES		○	NO
	»	Nausea	○	YES		○	NO
	»	Diarrhea	○	YES		○	NO
	»	Asthenia/fatigue (0-100%)	○	YES		○	NO
	»	Myalgia/body pain	○	YES		○	NO
	»	Outher (explain)					

Date of study enrolment	/ /

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CRF 01 - Eligibility Assessment

NAME OF PERSON filling out form:							
Participant name*							
Does this candidate have a situation that prevents him or her from participating in the SARS-CoV-2 / Covid-19 study?							
1.c EXCLUSION CRITERIA							
»	weight >120 kg	◯	YES	◯	NO		
»	presence of anti-SARS-CoV-2 antibodies **[PERFORM RAPID TEST]**	◯	YES	◯	NO	[response in 3 min. Result_____	
»	liver failure (has a doctor ever told you that you have liver failure?)	◯	YES	◯	NO		
»	blood-brain barrier disorder - recent head trauma < 14 days	◯	YES	◯	NO		
»	confirmed or probable pregnancy **[PERFORM RAPID TEST]**	◯	YES	◯	NO	[response in 3 min. Result_____	
»	breastfeeding	◯	YES	◯	NO		
»	use of coumarin anticoagulant (warfarin)	◯	YES	◯	NO		
»	ivermectin allergy	◯	YES	◯	NO		
If the candidate answered YES to at least one item above, thank them and exclude them from the study							
If the candidate answers NO to all of the above questions, proceed with the interview							
◯	**Asymptomatic individual (Eligible)**	**Absence of clinical signs suggestive of COVID-19 or influenza**					
◯	**Covid-19 or flu syndrome by other viruses (Ineligible)**	**Presence of clinical signs suggestive of COVID-19 or influenza**					
Are there any signs or symptoms of influenza/COVID-19? If yes, note and exclude from the study							
Is the candidate eligible for this study?		◯	YES	◯	NO	Reason:	
If yes, Explain the purpose of the study and invite them to sign the ICF							
Did the candidate agree to sign the IFC?		◯	YES	◯	NO		
OBS. If eligible, fill out Form 2 - for allocation notes based on randomization (packet number), SINGLE DOSE treatment, and follow-up							
SEND Form 1 for statistical analysis, for all included and excluded candidates.							
*Used during data collection only, for easy identification							

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CRF 02 - Baseline and follow-up data

Date	/ /2020	NAME OF PERSON RESPONSIBLE for completing the form and delivering the drug: ______________________________	
Participant name*			
SUS card number			
CPF number			
Birth date	/ /		
PACKET CODE (UNIQUE CODE)			
Sex	◯ Male	◯ Female	[Explain the need not to get pregnant within a month by adopting the abstinence, barrier (condom) or pharmacological method (contraceptive pill)]
Birth date	/ /		
Age	years		
Reported WEIGHT	kg	Reported HEIGHT cm	BMI
Home address:			
Neighbourhood		City:	State:______
Cell phone number, with area code:	( )		
Number of residents in the home:	adults and children)		
Number of rooms in the home ________			
Any of the residents had or have COVID-19?	◯ YES if yes, when?	◯ NO	
Do you wear a mask outside the home?	◯ YES ◯ Always	◯ Sometimes	◯ NO usa
Do you think you caught the COVID-19 virus in the last 14 days?	◯ YES When? ______ How? ______________	◯ NO	
Have you ever taken ivermectin? If yes, how often (when) and dose	◯ YES	◯ NO	if yes, when, reason and dose:

Does the participant have comorbidities and use medications?

» hypertension	◯ YES	◯ NO	medication:	
» diabetes	◯ YES	◯ NO	medication:	
» kidney disease	◯ YES	◯ NO	medication:	
» asthma	◯ YES	◯ NO	medication:	
» autoimmune disease (rheumatoid arthritis? systemic lupus erythematosus?)	◯ YES	◯ NO	Indicate which: medication:	
» allergy	◯ YES	◯ NO	Indicate:	medication:
» other	◯ YES	◯ NO	Indicate:	medication:

Are there any signs or symptoms of influenza/COVID-19? If so, note on which clinical days they occurred, with D1 being the first day of symptoms

» **Cough**	◯ YES	◯ NO
» **Headache**	◯ YES	◯ NO
» **Dyspnoe**	◯ YES	◯ NO
» **Fever**	◯ YES	◯ NO
» **Nasal discharge**	◯ YES	◯ NO
» **Sore throat**	◯ YES	◯ NO

LIKA / UFPE
CRF - Case Registry Form - F02
Version: 10 September 2020

Confidential due to Biotechnology subject to professional secrecy

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CRF 02 - Baseline and follow-up data

Date	/ /2020	NAME OF PERSON RESPONSIBLE FOR completing and delivering the drug:
Participant name*		

Are there any signs or symptoms of influenza/COVID-19? If so, note on which clinical days they occurred, with D1 being the first day of symptoms

» **Change in smell**	◯ YES	◯ NO
» **Change in taste**	◯ YES	◯ NO
» **Nausea**	◯ YES	◯ NO
» **Diarrhoea**	◯ YES	◯ NO
» **Asthenia/fatigue (0-100%)**	◯ YES	◯ NO
» **Myalgia (VAS 0 to 10)**	◯ YES	◯ NO
» **Other (explain)**		

In case of presence of any sign or symptom listed above, in the interval between the last visit and this one, forward this participant to the doctor at the FHU whose number is on the SUS card.

reported WEIGHT	kg	**GIVE the participant the capsule(s) contained in the packet as calculated by weight and witness ingestion with water**

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CRF 03 - Hospitalization follow-up

Date																			
SARS-CoV-2 - Covid-19 Trial registration number																			
Institution name																			
Name								Initials (XXX)__ __ ___											
Sex		◯	Male			◯	Female												
Birth date _____/_____/_____																			
Hospitalized?	◯	No	◯	Yes				Admission date ____/_____/_____											
Admitted to the IC	◯	No	◯	Yes				Discharge date ____/_____/_____											
Imaging exam showing ground glass opacity or other infiltrates?																◯	No	◯	Yes
Description of chest CT findings																			
» **Breathing** **[MEASURE SAT O_2%]**					◯	YES	Sat O_2 % _____											◯	NO
» Need for O_2 via nasal catheter or mask/mechanical ventilation?																◯	YES	◯	NO
» FiO_2 required_____ with date _____/_____/_____; Sat O_2 %					or		O_2 supplementation _____(in L/min). Start date: _____/_____/_____											
» FiO_2 required_____ with date and time _____/_____/_____;							O_2 supplementation _____(in L/min). Start date: _____/_____/_____											
» Need for mechanical ventilation?						◯	YES	Start date: _____/_____/___										◯	NO
» FiO_2 required_____ with date and time _____/_____/_____;							End date: _____/_____/_____											
» Use of vasoactives?					◯	YES												◯	NO
» Use of low-molecular-weight anticoagulant?								◯	YES	◯	NO								
Start date: _____/_____/_____																			
End date: _____/_____/_____																			
Fever on admission?					◯	YES	◯	NO	Reason:										
Medications prescribed in the period					◯	YES	◯	NO	Reason:										
Medications		Dose		route		Start date			End date										

		Date	Date	Date	Date	Date	Date
Exams performed							
ALT/GPT							
AST/GOT							
Bicarbonate							
Urea							
Creatinine clearance							
Chloride							
Potassium							
Total bilirubins							
Hematologic							
Red blood cells							
Hematocrit							
Hb							
Platelets							
Leucocytes							
Neutrophils							
Linphocytes							
Eosinophils							
OBS							
Coagulation							
D-dimer							
Prothrombin time							
INR							
Activated partial thromboplastin time							
Clinical summary							