Kingdom of Saudi Arabia
Ministry of National Guard - Health Affairs

المملكة العربية السعودية
وزارة الحرس الوطني – الشؤون الصحية

Informed Consent for Research Study – Interventional Studies

Study Title	:	**A Trial of Favipiravir in Adults with Mild Coronavirus Disease Covid-19**
Study No.	:	
ICF version and date:		**V2, 15/09/2020**
Principal Investigator	:	**Dr. Mohammad Bosaeed**
Sponsor	:	**King Abdullah International Medical Research Center (KAIMRC)**
Principal Investigator Address	:	**King Abdulaziz Medical City- Riyadh Department of Medicine (MC 1443) P. O. Box 22490 Riyadh 11426 +966(0)18011111 Ext. 17535. bosaeedmo@ngha.med.sa**

1. Introduction:

- You are being invited to take part voluntarily in a research study because you have a mild COVID-19 infection. We are studying an antiviral medication called FAVIPARAVIR. This antiviral drug is approved in other countries like Japan to be used for influenza virus. We want to study its effect on the COVID-19 infection. Many countries like USA, Japan Italy and India are doing similar studies to see the effect of this antiviral medication in decreasing the illness caused due to COVID-19 infection.

- Please take time to read this information carefully. Discuss it with any one you want for the right advice (This may include a friend, a relative or a family doctor).

2. Study Purpose:

- This is a research study. The purpose of this study is to measure the effect of this medication on time of viral shedding and the resolution of symptoms like tiredness and lack of energy, fever, cough, and shortness of breath, sore throat, nasal congestion, vomiting, diarrhea etc. This study will also measure how safe this medication is to be used in treating COVID19 infection.

3. Duration of Participation:

- If you agree to participate in the trial, you will be required to take the medication for maximum period of 7 days. You will be followed up every day for 14 days to monitor your condition. We will also check on you on day 28 for a follow up on your well-being.

4. Number of Subjects participating/ study Area and settings:

- In this research study 576 patients like you will be participating. This study will be conducted in King Abdulaziz Medical City -Riyadh and other hospitals across the Kingdom.

5. Study Procedures:

- You will be put in a group randomly (like flipping a coin) to antiviral Favipiravir or the Placebo group (these are pills that look like Faviparavir but they have no effect on your body or your infection.)
- You will receive Favipiravir (AVIGAN) or placebo 1800mg i.e. 9 tablets on the 1st day two times in a day, then from next day till day 7 the dose will change to 800mg i.e. 4 tablets, two times by mouth.

- You will have a 50% chance of receiving either the medication Faviparavir or placebo.

Patient responsibility:

- You will need to record all the doses of the medication you will take at home in the given medication log
- If you miss a dose ,please record it as missed dose
- At the end of 7 days, please kindly bring back the empty bottle or the bottle with missed pills. Also bring the medication log you used to record the pills you took.
- You will need to come back to your study doctor on the day 5, 10 and 15 counting from the day you signed this consent and we will collect blood samples with a swab from your throat, nose or a sputum sample.

6. When will my participation end?

You will take this medication for a maximum of 7 days only. We will follow-up with you every day to check on your health for 14 days. We will check again on day 28 to know your well-being.

7. Risks and inconveniences:

- Like with all other medications this medication can also have some side effects that are common. These include increase in uric acid levels, diarrhea, abnormal liver tests and decrease in neutrophil count(neutrophils are type of white blood cells in your body that help to fight infection)
- Some people might have an allergic reaction to any of the ingredients of this medication.
- As you are required to give blood for lab tests on day 5, 10 and 15, the blood draw can cause bruising or pain at the site of blood draw. In some people this can cause fainting and rarely there can be infection at the site of blood draw
- Pregnant women will not be enrolled in this study. Male participants are advised to use the most effective contraceptive method during their participation and 7 days after the treatment ends. **Complication**: If pregnancy took place when you were taking this medication, information from animal studies showed that this medication spreads to sperm and cause the death of embryo or cause growing defects in embryos.
- There might be unknown reactions that can take place that we do not know yet.
- You will be informed with any new information that becomes available and this may affect your desire to start or continue the study.

8. Important information regarding females participation in the study:

If you are pregnant or suspect pregnancy, please inform us, as we cannot include pregnant or

suspected pregnant females in this study.

9. Costs and compensation for participation in this study:

You will not receive any compensation for your participation in this trial. However, in the event of an illness or injury related to the study medication, all treating procedures, follow-ups, hospitalization, will be provided to you immediately.

10. Benefits:

Previous studies done in USA and JAPAN have shown that this medication had a positive effect in treating influenza virus.

You may or may not benefit directly from participating in this research, but your participation may help other patients with COVID-19.

This research study will increase the medical knowledge which will help to decide if FAVAPIRAVIR medication can be used in treatment of COVID-19 in the future.

11. Alternative Treatment(s):

You will be receiving the routine treatment as per the treating physicians during the course of the study and you will be made aware of any new treatment available for the disease.

12. Information about participation:

Your participation in this study is totally voluntary, you have the right to withdraw at any time you want without mentioning the reasons. If you do not want to take part, you will receive standard care provided by your doctor, and your decision about the study will not affect your current or future medical care.

The study doctor and the study sponsor have the right to withdraw you from the study if he decided that it's better for your medical condition. Or you did not comply with study requirements.

If you have any other diseases or adverse events the principal investigator will decide whether to continue with participation in the study or not.

13. Confidentiality and Authorization to collect, use and disclose Personal Medical Information:

All information related to you including personal and medical data provided and collected by the study doctor and recorded in the study records will be handled as confidential and no one except authorized research team at King Abdullah International Medical Research Center (KAIMRC), Sponsors, Institutional Review Board (IRB), Research Scientific Committee (RC), Ministry of Health auditors, the Saudi Food and Drug Administration (SFDA) and related personnel that can have access to record, review and analyze them.

All the information collected in subjects records belong to King Abdullah International Medical Research Center. In case any results of the study are published, your personal information will never be mentioned, it may be coded in symbols known for research team

14. Communication

In case of any research related inquiries or medical care during study, or any injuries, emergency cases feel free to contact the study principal investigator **Dr. Mohammad Bosaeed** through Phone number: **+966(0)18011111 Ext. 17535.**
In case you have enquiries related to your rights as a research subject you can contact the Institutional Review Board on Tel. **0114294432** or **011429376**

- I've been given the opportunity to discuss my questions about participating in this study and the research team has answered all my questions, if I have any further questions I will call **Dr. Mohammad Bosaeed**
- I understand that my participation in this research is voluntary and I know that I have the right to withdraw when I decide without affecting the medical care that I receive usually and also understand that the principal investigator has the right end my participation as it deems appropriate to me.
- And I also understand that non-compliance with research procedures and/or the visits dates might end my participation of this study.
- I understand that every clinical trial must be registered in a publicly accessible database before recruitment of the first subject.
- By signing this informed consent form I acknowledged that I did not give up any of my legal rights, also I confirm that I have received a sufficient information about the study and that I have read and understood the information in this informed consent form and I have had the opportunity to discuss the study and ask questions and have been satisfied with the received explanations.
- I understand that after signing this informed consent form I will receive a signed and dated copy.
- By signing and dating this informed consent form, I agree to participate in this research study.

Subject Name	**Signature**	**Date**
Name of the legal guardian Type if the patient is minor (less than 18 years)	**Signature**	**Date**
Name of the witness Type if the subject agrees verbally and he/she is illiterate	**Signature**	**Date**
Name of the Principal Investigator	**Signature**	**Date**
Person who discussed the consent	**Signature**	**Date**