

INFORMED CONSENT FORM

Name of Research Project: Evaluation of the Effectiveness and Safety of Adding Ivermectin to Treatment in Severe COVID19 Patients

Name of Coordinator Researcher: Prof. Dr. Nurullah OKUMUŞ

Dear Volunteer,

We invite you to be a volunteer in a voluntary study in which the efficacy and safety of the drug called ivermectin is evaluated.

This study is for research purposes. It has no profit aim in any way.

Clinical COVID19 disease caused by the new corona virus (SARS CoV-2) progresses from mild, self-limiting mild respiratory disease to severe pneumonia, multi-organ failure and death. The disease can be fatal in patients with severe prognosis, and currently used treatments may not provide full effectiveness in every patient.

Currently, the standard treatment recommended by the Ministry of Health in our country is used in all patients with severe COVID19 disease. In our research, in addition to this treatment, we will use ivermectin drug, which was previously used in parasites and some viral diseases in humans and has been shown to be effective against SARS CoV-2 virus in a new study. We think that ivermectin may also be effective in COVID19 patients and will help recovery in patients with severe prognosis.

A total of 60 (sixty) patients who were diagnosed with severe COVID19 disease and are > 18 years old will be included in the study. If you agree to volunteer in the study, the prescribed time for receiving treatment is 5 days. Participation in the study is entirely at your discretion, and you can withdraw from the study at any time. Your information recorded for the study will not be used elsewhere in any way.

In this study; Patients presenting with severe COVID19 infection clinical status will be given odd and even numbers in order of application. Odd numbers will be grouped as "study group" and even numbers as "control group".

If you are in the control group, you will receive Hydroxychloroquine (2x400 mg loading dose followed by 2x200 mg orally for a total of 5 days) ± Favipiravir (2x1600 mg loading dose followed by 2x600 mg, orally for a total of 5 days) ± Azithromycin (500mg on the first day followed by 250mg / day by mouth for a total of 5 days) treatment which is currently used in our country and recommended by the Scientific Committee of the Ministry of Health.

If you are in the study group, in addition to this treatment; Ivermectin, which we evaluated in our study, is suitable for oral use at a dose of 200 mcg/kg/day (9 mg between 36-50 kg, 12 mg between 51-65 kg, 15 mg between 66-79 kg, > 80 kg 200 mcg / kg) will be given to you orally or with the help of a catheter for five days in the form of a prepared solution .

The most common side effects during ivermectin treatment are fever, headache, dizziness, itching and rash. Skin reactions and asthma can be worsen. Rarely, neurological side effects such as encephalopathy, confusion and coma have been reported during the use of ivermectin. In our study, side effects will be monitored closely in all patients taking this drug, and if any side effects are observed, your treatment will be terminated. You volunteers who will participate in the study will also be informed about the side effects of drugs such as hydroxychloroquine, azithromycin and favipiravir in the reference treatment.

Some side effects can be seen in people with some genetic differences during the use of ivermectin. In our study, volunteers who will receive ivermectin will first be tested for these genetic differences (MDR-1 / ABCB1 and CYP3A4 mutations). It is entirely up to you whether to participate in this genetic study and the subsequent ivermectin efficacy and safety study. In people with these genetic differences, ivermectin metabolism may be disrupted and harmful effects of ivermectin may occur. If you are in the patient group to be given ivermectin and if these gene mutations are detected by genetic study, you will be excluded from the study due to the possibility of side effects.

Blood samples to be taken for genetic studies will be studied in the laboratories of Intergen company. After the study is completed, without your consent, the samples taken from you will be duly destroyed at the current center, in accordance with the law. The storage of the blood sample taken by you and its use in further studies are only subject to your consent. These examples can be stored for many years, provided that your name (identity information) is protected or destroyed.

If you allow to be taken your blood sample for genetic study, please sign only one of the options in the boxes below that is suitable for you.

I approve the use of the * coded blood sample taken by me only for this study investigating the efficacy and safety of Ivermectin use in COVID19 infection; I do not give consent for future studies related to possible COVID19 infection.

Name-Surname (by handwriting):

Signature:

I approve the use of the coded blood sample taken by me only for this study investigating the efficacy and safety of Ivermectin use in COVID19 infection; I would like to be informed again and give new approval for future studies related to possible COVID19 infection.

Name-Surname (by handwriting):

Signature:

I approve the use of the coded blood sample taken by me in other studies related to COVID19 infection, but I would like to be informed again and give new approval in other studies (including genetic studies) other than COVID19 infection.

Name-Surname (by handwriting):

Signature:

*** Coded sample:** *The sample taken from you is given a code number. Only the researcher knows the code number and only the researcher can access your identification information. Thus, your credentials are kept confidential.*

If you agree to voluntarily participate in this study; You have responsibilities such as cooperating with the researchers who conducted the study, providing accurate information (about your accompanying additional health problem, drug allergy, medications you are constantly using, etc.), your clinical situation, the treatment and methods applied, and not reporting the information about the results of the study to third parties.

If you agree to voluntarily participate in this study; Records that will reveal your identity will be kept confidential, will not be disclosed to the public, and your identity will be kept confidential even if the research results are published. In addition, the study monitors, reviewers, ethics committee and other relevant health authorities will have direct access to your original medical records, but this information will be kept confidential. By signing the written informed consent form, you or your legal representative will allow such access. You or your legal representative will be notified in a timely manner as soon as new information regarding the research topic becomes available that will affect your willingness to continue participating in the research.

If you agree to participate in the study, no payment will be made to you. However, against the possibility of any harm caused by the work, your health insurance will be taken out to compensate the damage and to make any necessary medical intervention.

Whether or not to take part in this study is entirely up to you. If you decide to participate this will be given to you to sign the written informed consent form. If you are unable to give consent or sign, consent and signature will be obtained from the person who is your legal representative.

Even if you sign this form right now, you are free to stop working at any time without giving a reason. If you make such a decision, your medical care will not be affected in any way.

I have read (or listened to) the above text, which contains the information that should be given to the volunteers before starting the research. I asked the researchers my questions on issues I thought were missing and got satisfactory answers. I am of the opinion that I understood all the written and oral statements submitted to me in detail. Ample time was given to decide whether I would like to participate in the study.

When I encounter a health problem during research; I know that I can reach the responsible researchers whose names and phone numbers are given below at any time.

Responsible researchers; Prof. Dr. Neşe DEMİRTÜRK (Phone: 0505 4775515), Ass. Prof. Dr. Rıza Aytaç ÇETİNKAYA (Phone: 0505 4382814), Prof. Dr. İsmail Yaşar Avcı (Phone: 0532 2927212, 0533 6689733)

Under these circumstances, I declare that I voluntarily accept to participate in the study titled "Evaluation of the Effectiveness and Safety of Adding Ivermectin to Treatment in Patients with Severe Course of COVID19", without any pressure or coercion, provided that confidentiality rules are observed.

The volunteer:

Name, surname:

Date:

Signature:

Legal representative:

Name, surname:

Date:

Signature:

The researcher making the information:

Name, surname:

Date:

Signature: