

Participant information sheet

An Invitation

You are invited to take part in a scientific study. In this document you will find a description of the study “Personalized science-based technologies in the diagnosis and therapy of SARS-CoV-2 as a possible risk factor in patients with rectal cancer”.

Please take the time to read this document carefully and decide whether you wish to participate in this study or not.

What is the purpose of this study?

You have been invited to participate in this scientific study because you suffer from a form of oncological pathology. At present, traditional therapy using chemotherapy, radiation therapy, immunotherapy, and surgery are the main methods of treating patients with this pathology in Uzbekistan.

It is well known that viruses are triggers of cancer in various forms of cancer. Previously, no studies have been conducted on the subject of eliminating the virus as a causative agent of the oncological process in already formed cancer, as well as the subsequent study of the effects of the therapy. A promising and unexplored direction in this area is the use of information approaches in the treatment of certain infections (bacterial, viral, fungal) in the human body using not the drug itself, but its information.

Do I have to take part in this study?

You can decide for yourself whether to participate in this study or not (it is your choice). If you decide to participate in the study, you will be asked to complete, sign, and date this patient or relative information form. Please keep it for your records, as it contains useful information about the study and the doctor's contact phone numbers. You can still refuse further participation in the study at any time without giving a reason, and your decision will not affect the quality of your further communication and treatment. You will be informed immediately if, at any time, additional information becomes available that may affect your consent to continue participating in the study.

What happens if I agree to participate in this study and what do I need to do?

If you agree to participate in this study, you will need to visit the City Branch of the Republican Specialized Scientific and Practical Medical Center of Oncology and Radiology, outpatient department, in agreement with the doctor conducting this study.

You will undergo:

- Collection of anamnesis data, physical examination, necessary laboratory tests provided for by the study protocol.
- Conducting medicament testing, which is a non-invasive procedure and is carried out by measuring the electrical conductivity of certain acupuncture points located on the patient's skin with the application of Ribavirin drug. Then, the tested drug is placed in a “device for remote transfer of information from the drug to the patient's body” and this device is placed on the surface of your body above the projection of various organs determined by the doctor conducting this study. The duration of the procedure varies and can take from two to five hours. You are placed on a couch lying down in a position that is comfortable for you. This way, you do not receive the

drugs internally. Information about the drug is introduced into your body using the device mentioned above.

- The only side effect that should be expected from the procedure is associated with the elimination of the pathogen from your body and this process usually manifests itself as slight weakness over the next two days. During the post-therapy process, you need to drink a large amount of plain water (up to 2 liters daily).

- A follow-up examination by the expert who is conducting is carried out in ten-fourteen days.

This concludes your participation in this study.

You can refuse the study at any time without explaining the reason, and your decision will not affect the quality of your further treatment carried out within the walls of the city branch of the Institute of Radiology and Oncology.

What are the possible disadvantages and risks?

The only side effect that should be expected usually manifests itself in slight weakness over the next two days.

What is the possible benefit of participating in the study?

The proposed intervention may have a positive effect on the course of colorectal cancer, since the cause that caused the cancer process and, apparently, supports the oncological process itself during its development is destroyed, as suspected.

Will my participation in the study be confidential?

Yes, all information obtained during the examination is considered confidential information, without further dissemination. If necessary, your doctor in charge of the study may contact your relatives or friends, as well as your attending physician or other medical personnel responsible for your treatment, to collect information about your health condition, if this is important for this study. You will have the right to access your personal data and make corrections through your physician in charge of the study. In case of premature termination of participation in the study, all information obtained up to this point will be used.

How will the results of the study be used?

The results of this study will be published in a medical journal. The information will be treated as confidential, and under no circumstances will your name be disclosed.

Insurance and cost of participation

The clinical trial, the medicament testing process and further therapy using a device for remote transfer of information from the drug to the patient's body will be free of charge for you. No material reward is provided for participation in the study.

Who evaluated this study?

The protocol of this study was reviewed and approved by the Ethics Committee under the Ministry of Health of the Republic of Uzbekistan No. 6 / 11-1917 dated 09/05/2024

Contact information.

If you have any questions, please contact your physician in charge of the study:

Dr. Djumaeva Naylya Erkinovna.

Thank you for considering participating in this study.

INFORMED CONSENT FORM

I, the undersigned, (full name)

residing at (address) give my voluntary

consent to participate in the study: "Personalized scientifically based technologies in the diagnosis and treatment of SARS-CoV-2 as a possible risk factor for the development of colorectal cancer." Research physician: Djumaeva NE

I received comprehensive explanations from the employee who discussed my participation in the study with me regarding the nature, purpose, and duration of this study.

I confirm that I have fully read and understood the attached information. I was provided with complete and understandable information for a research participant. I had the opportunity to ask any questions that arose.

I understand that participation in this study is voluntary. I can withdraw my consent at any time, without providing a reason, and this will not result in any undesirable consequences for my future communication and treatment.

I understand that authorized representatives of the regulatory organizations and the ethics committee may review some sections of my medical records related to my participation in this study. By my signature, I grant them the right to access my medical records.

I understand that information will be collected during this study, which will be treated as confidential. My name will never be disclosed to anyone.

I will not attempt to limit the possible use of the study results.

I acknowledge that, according to the legislation of the Republic of Uzbekistan, no financial compensation is provided to patients participating in research.

I agree to participate in this study and to cooperate with the research physician, Dr. Djumaeva NE, and, if necessary, with authorized employees from her research group. I undertake to immediately inform Djumaeva NE of any deviations from the norm that I notice.

I agree that my attending physician or other physicians responsible for my treatment will be informed of my participation in this study. I agree that my physician-investigator may contact my relatives, friends, attending physician, or other physicians responsible for my care to obtain information about my health if it is necessary for this study.

I have received a signed copy of this patient's information and consent form.

Full name

Date

Signature

This document was considered in the general list of documents of subjects under consideration by the Ethics Committee of the Republic of Uzbekistan and received approval from the commission.