

# SARS-CoV-2 is a possible risk factor for the development and progression of rectal cancer

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 28/07/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 28/07/2025	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Infectious agents account for 22% of cancer deaths in developing countries, compared with 6% in the industrialized world. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the cause of the COVID-19 pandemic, according to some data, can persist in the human body for an extended period. Recent studies suggest that standard pathogenic mechanisms are present for both SARS-CoV-2 and oncogenesis. SARS-CoV-2 exploits host immunity, stimulates signalling and oncogenic pathways, and may establish an oncogenic microenvironment. Therapy for tumor processes includes chemotherapy, radiation therapy, surgical treatment, immunotherapy, hormonal therapy, and others. However, to date, no attempts have been made to eliminate the virus as a risk factor in patients with already formed oncological pathology.

**Aim:** To carry out a clinical trial to determine the capabilities of information methods in the diagnosis of SARS-CoV-2 and the treatment of patients with rectal cancer for the purpose of eliminating the virus, while the diagnosis of the infectious agent is based on measuring the electrical conductivity at specific acupuncture points located on the surface of the human body (non-invasive approach), and the therapy of the viral infection is carried out using "a device for transferring the information from the drug to a human body".

### Who can participate?

Before administering a traditional therapy, we will conduct a study of 60 adult patients with stage II-III rectal cancer.

### What does the study involve?

The study participants are patients of the outpatient department of the city department of the Republican oncology with a confirmed diagnosis of rectal cancer stage II-III. The principal investigator has full access to the patient's medical records. Patients are randomized using the sealed envelope method. Patients of the main group, after familiarization with the proposed method of exposure and signing written informed consent, undergo medicament testing using RNA polymerase nosode in C30 dilution, Ribavirin (200 mg) and Dexamethasone (0.5 mg). Taking into consideration the localization of the cancer process, the known lymphogenous pathways of metastasis, as well as the organs most frequently affected by metastases in rectal cancer, the following acupuncture points were chose for medicament testing: Ly14, Ly10, Ly8, Ly7, Ly4, Kr8d (D, S), Ni 1-3, Di1b, Du1b, Le2, Le5, Lu10c, Ge1b - to measure the level of electrodermal activity

of acupuncture points, where the Ly designates the lymphatic system meridian, Kr - the circulation meridian, Ni –kidney meridian, Di-colon meridian, Du- intestine meridian, Le-lever meridian, Lu- lungs meridian, Ge-meridian of articular degeneration( Voll,1956). Then patients with a registered positive response to mentioned drugs undergo exposure using a "device for transferring information from the drug to the human body", into which Ribavirin (200 mg) is placed, and the device itself is sequentially positioned over the projection of the patient's organs associated with the acupuncture points at which a positive response to the tested drugs was obtained during medicament testing. The total exposure time of both procedures is from 3 to 5 hours. After completion of the exposure, the investigator prepares a report on the exposure carried out, including a detailed description of the procedure, which is saved in the patient's medical history. A repeat examination of the patient using medicament testing is carried out after 10-14 days to assess the response of the RNA polymerase nosode, ribavirin and dexamethasone at the studied acupuncture points A negative response to these drugs, determined during medicament testing, confirms the transfer of information from ribavirin to the patient's body and may indirectly indicate the elimination of SARS-CoV-2 from the patient's body. Further monitoring of patients is carried out by oncologists of the outpatient department of the city department of the Republican oncology according to the protocols for managing patients with rectal cancer. Patients in the control group are not exposed to the described procedure and receive treatment according to the protocols for this group. The results of the exposure are assessed by the outcomes of the disease during the observation of patients.

What are the possible benefits and risks of participating?

The principal investigator(PI) is a specialist in medicament testing with 34 years of experience and has a number of publications confirming the effective use of new information technology in a number of diseases of an infectious nature(The list is attached).The proposed method of information therapy has been used by the PI since 2004 and is also supported by a number of publications. The only side effect from using information about the drug instead of using the drug itself is a slight weakness that is registered by the patient in the next two days and which stopped on its own.

The advantage of this effect is the speed of action obtained - a single exposure without the need for routine administration, ensuring the absence of side effects that occur with the traditional method of administering the drug. In this trial, it is expected that eliminating the virus involved in the oncological process can influence the oncological process and contribute to inhibiting the metastatic process and also prevent cancer recurrence in the future.

Where is the study run from?

The outpatient department of the city department of the Republican oncology, Uzbekistan.

When is the study starting and how long is it expected to run for?

December 2024 to December 2029

Who is funding the study?

Investigator initiated and funded

Who is the primary contact?

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## Contact information

**Type(s)**

Public, Scientific, Principal investigator

**Contact name**

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**Additional identifiers****Protocol serial number**

6/11-1917

**Study information****Scientific Title**

Personalized, scientifically based Technologies in the diagnosis and treatment of SARS-CoV-2 as a possible Rectal Cancer risk factor

**Acronym**

PETCVORC

**Study objectives**

To confirm the possibilities of medicament testing in the diagnosis of SARS-CoV-2, as a potential risk factor for the development of rectal cancer by comparing the treatment results of patients in the main and control groups.

To confirm the possibilities of application of the "device for transferring information from a drug to the human body" in the therapy of SARS-CoV-2, as a potential risk factor for the development of rectal cancer by comparing the treatment results of patients in the main and control groups.

**Ethics approval required**

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**Ethics approval(s)**

approved 05/09/2024, Ethical Committee of the Ministry of Health of the Republic of Uzbekistan (45,Oybek str., Tashkent, 100015, Uzbekistan; +99871 256 45 04; farmkomitet@ssv.uz), ref: 6/11-1917

**Study design**

Single-blind randomized controlled trial

**Primary study design**

Interventional

## **Study type(s)**

Diagnostic, Treatment, Efficacy

## **Health condition(s) or problem(s) studied**

Patients with rectal cancer stages II-III

## **Interventions**

Participants are randomized individually in a 1:1 ratio to undergo medicament testing using a nosode of RNA polymerase in C30 dilutions (a homeopathic drug), Ribavirin (Copegus, Roche, 200mg tablets), and Dexamethasone (0,5 mg.tablets) in the main group. In the control group of patients, a Glucose tablet (500 mg) is used as a placebo for medicament testing.

In the main group of patients, if a positive response to these drugs is observed, Ribavirin (200 mg) is placed in the "device for transferring information from a drug to the human body", and exposure is carried out.

A repeat medicament test is performed in patients from the main group 10-14 days after using the "device for transfer information for a drug to the human body".

Follow-up care will be the same for both study groups and will be performed by the institution's oncologist according to the institution's protocols for managing rectal cancer stages II-III.

Randomization will be performed by authorized personnel (PI or authorized person) through the CTU Clinical Data Management System (REDCap).

## **Intervention Type**

Device

## **Phase**

Phase II

## **Drug/device/biological/vaccine name(s)**

The electroacupuncture diagnostic device measures the electrical conductivity of acupuncture points using the Akuport M1+ (Kindling, Germany). "Device for transferring information from a drug to a patient's body" (Patent of Russia, 2001).

## **Primary outcome(s)**

Overall treatment outcome based on the absence of recurrence (local recurrence, distant metastases) of the disease for 5 years

## **Key secondary outcome(s)**

Patient-Reported Outcomes:

1. Quality of Life (QoL): Assessed by using the FACT-C (Functional Assessment of Cancer Treatment – Colorectal) to assess overall well-being.
2. Functional Outcomes: Assess bowel function (including issues like incontinence or constipation), urinary function (including continence or frequency), and sexual function.
3. Symptom Burden: Evaluates the presence and severity of symptoms like pain, fatigue, and other cancer-related symptoms.
4. Patient Satisfaction and Involvement: Evaluates patients' satisfaction with their treatment and their level of involvement in decision-making.

Clinical Outcomes:

1. Recurrence: to evaluate the local recurrence (in the rectum), distant recurrence (spread to other parts of the body), and overall recurrence rate.
2. Second Primary Cancers: Monitors for the development of new cancers, including colon

cancer, small intestine cancer, and anal cancer.

3. Overall Survival: The time from diagnosis until death from any cause.

4. Disease-Free Survival: The time from diagnosis to the first recurrence of cancer.

5. Tumor Regression Grade (TRG): Assesses the extent of tumor regression after treatment, using the Mandard classification.

### **Completion date**

01/12/2029

## **Eligibility**

### **Key inclusion criteria**

1. Undergoing outpatient surveillance, of both sexes, over 18 years of age

2. The confirmed diagnosis of rectal cancer stage II-III of the disease

3. The participant signed a written informed consent to participate in the study

4. Patients who responded positively to the RNA polymerase nosode in dilution C30, to drugs Ribavirin and Dexamethasone in the process of medicament testing

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Upper age limit**

65 years

### **Sex**

All

### **Key exclusion criteria**

1. Inability or refusal of the patient to comply with the protocol requirements

2. The need to prescribe drugs to the patient that are not allowed for use in the study

3. The occurrence of an adverse event

4. The patient's desire to terminate the study early for any reason

5. Cases not specified in the protocol, when the investigator believes that the patient's continued participation in the study is harmful to them

### **Date of first enrolment**

30/12/2024

### **Date of final enrolment**

01/12/2029

# Locations

## Countries of recruitment

Uzbekistan

## Study participating centre

**The Research Institute of Virology of the Republican Specialized Scientific and Practical Medical Center of Epidemiology, Microbiology, Infectious and Parasitic Diseases of the Republic of Uzbekistan**

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## Study participating centre

**Tashkent City Branch of the Republican Specialized Scientific and Practical Center of Oncology and Radiology.**

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# Sponsor information

## Organisation

The Research Institute of Virology of the Republican Specialized Scientific and Practical Medical Center of Epidemiology, Microbiology, Infectious and Parasitic Diseases of the Republic of Uzbekistan

# Funder(s)

## Funder type

Other

## Funder Name

Investigator initiated and funded

# Results and Publications

## Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date.

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>			28/07/2025	No	Yes