ISRCTN12078175 https://doi.org/10.1186/ISRCTN12078175

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

Submission date
17/07/2025

Recruitment status
Recruiting

Registration date
28/07/2025

Overall study status
Ongoing

Last Edited
28/07/2025

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] 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?
Naylya Djumaeva, MD, PhD, naila.djumaeva@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Naylya Djumaeva

ORCID ID
https://orcid.org/0000-0001-6850-465X

Contact details
Yangi Shahar 7A
Tashkent
Uzbekistan
100194
+998 977411955
naila.djumaeva@gmail.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

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
Ethics approval required

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
Yangi Shahar 7A
Tashent
Uzbekistan
100194

Study participating centre
Tashkent City Branch of the Republican Specialized Scientific and Practical Center of Oncology and Radiology.
Bogistan str., 1
Tashkent
Uzbekistan
100070

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?
Participant information sheet			28/07/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes