# Effects of gene expression pattern and RAS /BRAF mutations on the course of colorectal cancer

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
19/10/2015		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
20/10/2015	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
18/02/2019	Cancer			

#### Plain English summary of protocol

Background and study aims

Colorectal cancer, otherwise known as bowel cancer, is a disease where cancerous tumors develop in the large bowel (colon cancer) and cancer of the back passage (rectal cancer). Currently, histological characteristics of the tumor (i.e. its structure) and whether there are mutations to the KRAS or BRAF genes are used to predict the likely clinical course of colorectal cancer (i.e. the prognosis). Analysis of the expression profile of the tumor (a test that identifies which genes have been mutated) can increase the prognostic significance of molecular characteristics (distinguishing features of the individual cancer cells) for colorectal cancer. The aim of this study is to find out how well this new technology can help in the prognosis of this disease.

#### Who can participate?

Adults with potentially curable colorectal cancer that have not had chemotherapy and/or radiotherapy before surgery.

#### What does the study involve?

Tumors that have been removed from patients though surgery have their expression profile analysed. After this analysis, they are assigned to one of five different subtypes, including, stem-like, inflammatory, transit-amplifying, goblet-like and enterocyte. Patients with stage 1 cancer are then followed up three years after the surgery. Patients with stage III-IV are treated with chemotherapy according to common oncological practice. Patients with stage II receive either chemotherapy or not depending upon the decision of a chemotherapist. Follow up for all patients in the study is 3 years after surgery to see how long they survived disease free, how long it took them to relapse (if they did so) and how long did they survive for after surgery.

What are the possible benefits and risks of participating? There are no risks to participating.

Where is the study run from?

FGBU "State scientific centre of coloproctology" Ministry of Health of Russia

When is the study starting and how long is it expected to run for? November 2015 to October 2021

Who is funding the study? Ministry of Health of Russia

Who is the main contact?

- 1. Dr. Natalia Pospekhova (scientific)
- 2. Dr. Alexei Tsukanov (scientific)

## Contact information

#### Type(s)

Scientific

#### Contact name

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## Additional identifiers

#### Protocol serial number

N/A

# Study information

#### Scientific Title

The gene expression pattern and RAS/BRAF mutation status of tumor as a prognostic factor for colorectal cancer

#### **Study objectives**

The study hypothesis is based on the idea that the gene expression profile and RAS/BRAF status of the tumor can be prognostic factors of the clinical course of colorectal cancer disease

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

FGBU "State scientific centre of coloproctology" Ministry of Health of Russia Ethics Committee Nº27, 13/10/2015

#### Study design

Prospective cohort study

#### Primary study design

Interventional

#### Study type(s)

Screening

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

Colorectal cancer

#### Interventions

Tumors of operated patients will be assessed for expression profile and somatic KRAS/BRAF mutations. All cases will be then assigned to one of five different subtypes, as described Sadanandam and co-authors in 2013 (doi:10.1038/nm.3175):

- 1. Stem-like
- 2. Inflammatory
- 3. Transit-amplifying
- 4. Goblet-like
- 5. Enterocyte

Patients with stage I will undergo follow up only. Patients with stage III-IV will be treated with chemotherapy according to common oncological practice. Patients with stage II will either receive chemotherapy or not on dessision of chemotherapist.

Follow up for all patients in the study is 3 years after surgery.

#### Intervention Type

Genetic

#### Primary outcome(s)

Disease-free survival (DFS)

#### Key secondary outcome(s))

- 1. Overall survival (OS)
- 2. Time to relapse (TTR)

#### Completion date

31/10/2021

# **Eligibility**

#### Key inclusion criteria

Potentially curable colorectal cancer

#### Participant type(s)

**Patient** 

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

All

#### Key exclusion criteria

- 1. Participants that have had preoperative chemotherapy and/or radiotherapy
- 2. Patient that refuse to follow the study protocol

#### Date of first enrolment

01/11/2015

#### Date of final enrolment

31/10/2021

## **Locations**

#### Countries of recruitment

**Russian Federation** 

#### Study participating centre

FGBU "State scientific centre of coloproctology" Ministry of Health of Russia

2, Salyama Adilya str.

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**Russian Federation** 

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# Sponsor information

#### Organisation

FGBU "State scientific centre of coloproctology" Ministry of Health of Russia

#### **ROR**

https://ror.org/04rbazs75

# Funder(s)

## Funder type

Research organisation

#### **Funder Name**

FGBU "State scientific centre of coloproctology" Ministry of Health of Russia

# **Results and Publications**

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

#### **Study outputs**

Output type	Details	Date created Da	ate added	Peer reviewed?	Patient-facing?
Results article	results	26/06/2018		Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11	1/11/2025	No	Yes