

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

Submission date 19/10/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/10/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/02/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data

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 through 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 №27, 13/10/2015

Study design

Prospective cohort study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Screening

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 decision of chemotherapist.

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

Intervention Type

Genetic

Primary outcome measure

Disease-free survival (DFS)

Secondary outcome measures

1. Overall survival (OS)

2. Time to relapse (TTR)

Overall study start date

01/11/2015

Completion date

31/10/2021

Eligibility

Key inclusion criteria

Potentially curable colorectal cancer

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

300

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.

Moscow

Russian Federation

123423

Sponsor information

Organisation

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

Sponsor details

2, Salyama Adilya str.

Moscow

Russian Federation

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Sponsor type

Research organisation

Website

<http://www.gnck.ru/>

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

Publication and dissemination plan

We are planning to publish preliminary results of the investigation in one of the BioMed Central journals in 2017.

Intention to publish date

01/06/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	26/06/2018		Yes	No