ISRCTN18093312 https://doi.org/10.1186/ISRCTN18093312

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

Registration date
20/10/2015

Overall study status
Completed

Last Edited
18/02/2019

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 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
Dr Natalia Pospekhova

ORCID ID
https://orcid.org/0000-0001-5255-5065

Contact details
FGBU "State scientific centre of coloproctology" Ministry of Health of Russia
2, Salyama Adilya str.
Moscow
Russian Federation
123423

Type(s)
Scientific

Contact name
Dr Alexei Tsukanov

ORCID ID
https://orcid.org/0000-0001-8571-7462

Contact details
FGBU "State scientific centre of coloproctology" Ministry of Health of Russia
2, Salyama Adilya str.
Moscow
Russian Federation
123423

Additional identifiers

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

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.
Moscow
Russian Federation
123423

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