

Effects of mutations in KRAS and BRAF gene and histological parameters on the clinical course of disease in patients with metastatic colorectal cancer

Submission date 04/11/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 20/12/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 12/02/2019	Condition category Cancer	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

105/08/10

Study information

Scientific Title

The influence of mutation status in KRAS and BRAF gene according to the classical histological parameters of tumor as a predictive factor of the aggressive course of disease in metastatic colorectal cancer: a single centre, prospective, cohort trial

Study objectives

Knowledge of mutation status of KRAS and BRAF genes in addition to classical prognostic factors (histological characteristics of tumor and number of affected regional lymph nodes) improves the prediction of the aggressive course of disease in metastatic colorectal cancer to determine the start and the type of systemic therapy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The National Medical Ethics Committee, Ministry of Health, Republic of Slovenia, approved on the 26th August 2010 (ref: 105/08/10)

Study design

Single centre prospective cohort study

Primary study design

Interventional

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

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

Health condition(s) or problem(s) studied

Metastatic colorectal cancer

Interventions

Patients with metastatic colorectal adenocarcinoma will be treated with combination chemotherapy and targeted drugs in accordance with the guidelines for the systemic treatment of metastatic colorectal carcinoma and reviewed in accordance with good clinical practice and recommendations. The efficacy of treatment will be assessed in terms of RECIST criteria (version 1.1, Eur J Cancer 2009). During the treatment toxicity will be recorded according the Common Terminology Criteria for Adverse Events (CTCAE), version 4.02. In histological preparations, we will search for radical resection, the presence of vascular and perinevral invasion, lymphatic

invasion, stage T, differentiation of tumor, number of affected regional lymph nodes. Molecular analysis for the presence of mutations in KRAS and BRAF gene we will do on the existing primary tumor or metastases, or in bioptic samples of primary tumor or metastases.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Progression-free survival (PFS)
2. Response rate (Response Evaluation Criteria in Solid Tumors [RECIST]) in correlation with histological parameters of tumor tissue, KRAS and BRAF status

Secondary outcome measures

Overall survival (OS)

Overall study start date

29/11/2010

Completion date

31/12/2013

Eligibility**Key inclusion criteria**

1. Written informed consent
2. Histologically confirmed colorectal cancer
3. Diagnosis of metastatic disease
4. Age 18 to 75 years
5. Eastern Cooperative Oncology Group (ECOG) performance score 0 - 2
6. Life expectancy of at least 3 months
7. Primary tumor with described histological features
8. Histology available for further analysis and molecular diagnostics
9. Determination of BRAF mutations in KRAS gene before starting treatment
10. Adequate haematological function (ANC greater than or equal to $1.5 \times 10^9/L$, platelets greater than or equal to $100 \times 10^9/L$, Hb greater than or equal to 90 g/L)
11. Adequate liver function (serum bilirubin less than or equal to $1.5 \times ULN$, AST/ALP less than or equal to $2.5 \times ULN$)
12. In case of liver metastases less than $5 \times ULN$, adequate renal function (calculated creatinine clearance greater than or equal to 50 mL/min)

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

400 patients

Key exclusion criteria

1. ECOG performance score greater than 2
2. Participation in another clinical trial within 30 days prior to entering this study
3. Known hypersensitivity to any of the study drugs
4. Clinically significant cardiovascular disease (myocardial infarction less than or equal to 6 months before treatment start
5. Unstable angina
6. Uncontrolled hypertension
7. Arrhythmia requiring medication
8. Clinically significant renal disease (creatinine clearance less than 30 ml/min)
9. Liver cirrhosis Child B and C
10. Psychiatric disability to be clinically significant precluding informed consent
11. Evidence of any other disease
12. Metabolic dysfunction or laboratory findings, which give a suspicion of a disease or condition that contraindicates the use of any investigational drugs or means a higher risk for treatment-related complications

Date of first enrolment

29/11/2010

Date of final enrolment

31/12/2013

Locations

Countries of recruitment

Slovenia

Study participating centre

Zaloska 2

Ljubljana

Slovenia

1000

Sponsor information

Organisation

Institute of Oncology Ljubljana (Slovenia)

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Sponsor type

Research organisation

ROR

<https://ror.org/00y5zsg21>

Funder(s)**Funder type**

Research organisation

Funder Name

Institute of Oncology Ljubljana (Slovenia)

Results and Publications**Publication and dissemination plan**

The article will be published in March 2019.

Intention to publish date

01/03/2019

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration