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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	[_] Prospectively registered [_] Protocol
Registration date 20/12/2010	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 12/02/2019	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 x 10/9L, platelets greater than or equal to 100 x 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 x ULN, AST/ALP less than or equal to 2.5 x ULN
12. In case of liver metastases less than 5 x 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
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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