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Safety assessment of treatment with bevacizumab in metastatic colorectal cancer

Submission date 14/03/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 09/11/2010	**Overall study status** Completed	
Last Edited 09/11/2010	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
1.0.10.10.2009

Study information

Scientific Title
Safety assessment of treatment with bevacizumab in metastatic colorectal cancer: an observational study

Study objectives

This is an observational study recording bevacizumab toxicity according to the Common Terminology Criteria for Adverse Events (CTCAE) version 4.02 and the management of toxicity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The National Medical Ethics Committee at the Ministry of Health, Republic of Slovenia approved on the 21st January 2010 (ref: 115/11/09)

Study design
Observational study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Metastatic colorectal cancer

Interventions
This is a non-interventional, observational study. Patients with metastatic colorectal cancer will be treated with standard chemotherapy in combination with bevacizumab, with a dose of 5 mg /kg every 2 weeks or 7.5 mg/kg every 3 weeks in first-line therapy, and 10 mg/kg every 2 weeks or 15 mg/kg every 3 weeks in second-line therapy for 6 months and then according to RECIST criteria for response with maintenance therapy with bevacizumab until progression of disease, unaccetable toxicity or the patient refuses further treatment. During the treatment toxicity of bevacizumab, hypertension, proteinuria, haemorrhage, venous thrombosis, gastrointestinal perforation, hypersensitivity reaction, will be recorded according the Common Terminology Criteria for Adverse Events (CTCAE), version 4.02.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Bevacizumab

Primary outcome(s)
Safety of treatment with bevacizumab and management of toxicity, measured after each cycle of therapy

Key secondary outcome(s))
1. Response rate (RECIST), measured every 3 months
2. Progression- free survival (PFS), measured every 3 months
3. Overall survival (OS), measured every 3 months

Completion date
31/12/2011

Eligibility

Key inclusion criteria
1. Written informed consent
2. Histologically confirmed colorectal cancer
3. Diagnosis of metastatic disease
4. Aged 18 to 75 years, either sex
5. Eastern Cooperative Oncology Group (ECOG) performance score 0 - 2
6. Life expectancy of at least 3 months
7. Adequate haematological function (absolute neutrophil count [ANC] greater than or equal to 1.5 x 10^9 L, platelets greater than or equal to 100 x 10^9 L, haemoglobin [Hb] greater than or equal to 90 g/L)
8. Adequate liver function (serum bilirubin less than or equal to 1.5 x upper limit of normal [ULN], aspartate aminotransferase [AST]/alkaline phosphatase [ALP] less than or equal to 2.5 x ULN, in case of liver metastases less than 5 x ULN)
9. Adequate renal function (calculated creatinine clearance greater than or equal to 50 mL/min)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
75 years

Sex
All

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, unstable angina, uncontrolled hypertension, arrhythmia requiring medication)
5. Known coagulopathy
6. Proteinuria greater than 500 mg/24 hours
7. Chronic use of full dose oral or parenteral anticoagulants
8. High dose of aspirin (greater than 325 mg/day)
9. Anti-platelet drugs or known bleeding diathesis

10. Psychiatric disability to be clinically significant precluding informed consent
11. Evidence of any other disease
12. Metabolic dysfunction or laboratory findings that 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
22/03/2010

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
Slovenia

Study participating centre
Zaloska 2
Ljubljana
Slovenia
1000

Sponsor information

Organisation
Institute of Oncology Ljubljana (Slovenia)

ROR
https://ror.org/00y5zsg21

Funder(s)

Funder type
Research organisation

Funder Name
Institute of Oncology Ljubljana (Slovenia)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration