

Monitoring of treatment with bevacizumab in patients with metastatic colorectal cancer

Submission date 13/08/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/09/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 27/09/2010	Condition category Cancer	<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

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Additional identifiers

Protocol serial number
71/12/07

Study information

Scientific Title
Monitoring of treatment with bevacizumab in patients with metastatic colorectal cancer: a single centre observational study

Study objectives
Observational study, recording safety according to the National Cancer Institute Common Toxicity Criteria (NCI CTC), version 3.0 and evaluating efficacy in standard clinical practice.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The National Medical Ethics Committee, Ministry of Health, Republic of Slovenia approved on the 11th December 2007 (ref: 71/12/07)

Study design

Single centre observational study, retrospective to December 2007 and prospective from December 2007 onwards

Primary study design

Observational

Study type(s)

Screening

Health condition(s) or problem(s) studied

Metastatic colorectal cancer

Interventions

Non-interventional, observational study.

Patients with metastatic colorectal cancer are treated with standard chemotherapy in combination with bevacizumab as per SmPC. During the treatment adverse events of special interest to bevacizumab (high blood pressure, haemorrhage, thromboembolism, proteinuria, GI perforation, neutropenia, infection etc.) are recorded according the National Cancer Institute Common Toxicity Criteria (NCI CTC), version 3.0.

Assessments are performed at baseline, 3 and 6 months, thereafter follow-up is every 3 months (3 years follow-up).

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Safety of treatment with bevacizumab
2. Response rate: Response Evaluation Criteria in Solid Tumors (RECIST)
3. Rate of radical surgical resection (R0 resection)

Key secondary outcome(s)

1. Progression- free survival (PFS)
2. Overall survival (OS)

Completion date

31/12/2012

Eligibility

Key inclusion criteria

1. Written informed consent (for prospective part of the study)
2. Histologically or cytologically confirmed colorectal carcinoma with evidence of metastasis
3. Age 18 - 75 years
4. Eastern Cooperative Oncology Group (ECOG) performance score 0 - 2
5. Adequate haematological and organ function

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Clinical evidence of brain metastases
2. Clinically significant cardiovascular disease. Examples:
 - 2.1. Cerebrovascular accident (CVA) less than or equal to 6 months before treatment start
 - 2.2. Myocardial infarction less than or equal to 6 months before treatment start
 - 2.3. Unstable angina
 - 2.4. New York Heart Association (NYHA) greater than or equal to grade 2 chronic heart failure (CHF)
 - 2.5. Arrhythmia requiring medication
 - 2.6. Uncontrolled hypertension
3. Current or recent (within 10 days prior to first dose of bevacizumab) use of full-dose oral or parenteral anticoagulants or thrombolytic agent for therapeutic (as opposed to prophylactic) purposes
4. History of thromboembolic or haemorrhagic events within 6 months prior to treatment
5. Evidence of bleeding diathesis or coagulopathy
6. Serious, non-healing wound, ulcer, or bone fracture
7. Major surgical procedure, open biopsy or significant traumatic injury within 28 days prior to treatment
8. Evidence of any other disease, metabolic dysfunction, physical examination finding or laboratory finding giving reasonable suspicion of a disease or condition that contraindicates the use of bevacizumab or puts the patient at high risk for treatment-related complications

Date of first enrolment

31/12/2007

Date of final enrolment

31/12/2012

Locations

Countries of recruitment

Slovenia

Study participating centre

Zaloska cesta 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
	Participant information sheet				

