

# Monitoring of treatment with bevacizumab in patients with metastatic colorectal cancer

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