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Monitoring of treatment with bevacizumab in patients with metastatic colorectal cancer

Submission date
13/08/2010

Recruitment status
No longer recruiting

Registration date
27/09/2010

Overall study status
Completed

Last Edited
27/09/2010

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Screening

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

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

Overall study start date
31/12/2007

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
400

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)

Sponsor details
Zaloska cesta 2
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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
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration