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Safety assessment of treatment with cetuximab in metastatic colorectal cancer patients

Submission date 26/01/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 04/02/2010	**Overall study status** Completed	
Last Edited 04/02/2010	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
01/08 at ARRS

Study information

Scientific Title
Safety assessment of treatment with cetuximab in metastatic colorectal cancer patients: An observational study

Study objectives
Observational study, recording skin toxicity of cetuximab according to the National Cancer Institute Common Toxicity Criteria (NCI CTC), version 3.0, and to determine the best management of skin toxicity of cetuximab

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 of May 2009 (ref: 215/05/09)

Study design
Single centre observational toxicity study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
Non-interventional, observational study
Patients with metastatic colorectal cancer will be treated with standard chemotherapy in combination with cetuximab, with loading dose of 400 mg/m2 and following weekly dose of 250 mg/m2 6 months and then according to RECIST criteria for response with maintenance therapy with cetuximab until progression of disease, unacceptable toxicity or the patient refuses further treatment. During the treatment skin toxicity of cetuximab- acneiform rash, nail changes, hypertrichosis, teleangiectasias, pruritus, paronychia, will be recorded according the National Cancer Institute Common Toxicity Criteria (NCI CTC), version 3.0.
Assessments will be performed at baseline, every week during weekly cetuximab therapy, every two weeks during maintenance therapy with cetuximab, during follow up every 3 months until the progression of disease.
The total duration of follow up will be 3 years

Intervention Type

Other

Phase
Not Applicable

Primary outcome measure
1. Safety of treatment with cetuximab
2. Management of skin toxicity of cetuximab

Secondary outcome measures
1. Response rate (RECIST)
2. Progression- free survival (PFS)
3. Overall survival (OS)

Overall study start date
01/06/2009

Completion date
31/12/2011

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. ECOG performance score 0- 2
6. Life expectancy of at least 3 months
7. Adequate haematological function (ANC ≥1.5 x 10/9L, platelets ≥ 100 x 10/9/L, Hb ≥ 90g/L)
8. Adequate liver function (serum bilirubin ≤ 1.5 x ULN, AST/ALP ≤ 2.5 x ULN, in case of liver metastases < 5 x ULN)
9. Adequate renal function (calculated creatinine clearance ≥ 50 mL/min)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Total of 250 patients

Key exclusion criteria

1. ECOG performance score > 2
2. Prior treatment with cetuximab
3. Participation in another clinical trial within 30 days prior to entering this study
4. Known hypersensitivity to any of the study drugs
5. Clinically significant cardiovascular disease
5.1. Myocardial infarction ≤ 6 months before treatment start
5.2. Unstable angina
5.3. Uncontrolled hypertension
5.4. Arrhythmia requiring medication
5. Clinical evidence or confirmed brain metastases
6. Psychiatric disability to be clinically significant precluding informed consent
7. Evidence of any other disease, 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
01/06/2009

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
Slovenia

Study participating centre
Zaloska 2
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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
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