

Safety assessment of treatment with cetuximab in metastatic colorectal cancer patients

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Janja Ocvirk

Contact details
Zaloska 2
Ljubljana
Slovenia
1000
+386 (0)15879221
jocvirk@onko-i.si

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

1. Safety of treatment with cetuximab
2. Management of skin toxicity of cetuximab

Key secondary outcome(s)

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

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 $\geq 1.5 \times 10^9/L$, platelets $\geq 100 \times 10^9/L$, Hb $\geq 90g/L$)
8. Adequate liver function (serum bilirubin $\leq 1.5 \times ULN$, AST/ALP $\leq 2.5 \times ULN$, in case of liver metastases $< 5 \times ULN$)
9. Adequate renal function (calculated creatinine clearance $\geq 50 \text{ mL/min}$)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

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