Safety assessment of treatment with cetuximab in metastatic colorectal cancer patients

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 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 \geq 1.5 x 10/9L, platelets \geq 100 x 10/9/L, Hb \geq 90g/L)
- 8. Adequate liver function (serum bilirubin \leq 1.5 x ULN, AST/ALP \leq 2.5 x ULN, in case of liver metastases < 5 x ULN)
- 9. Adequate renal function (calculated creatinine clearance \geq 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 \leq 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)

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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