A Survey of Medical Oncologist’s Opinions and Perceptions Regarding the Management of Dermatologic Toxicities among mCRC Patients Treated with Vectibix (20160258)

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/21200

EU PAS number

EUPAS18060

Study ID

21200

DARWIN EU® study

No

Study countries

United States

Study description

The study population consisted of practicing oncologists in the United States who treat patients with mCRC. Oncologists were recruited from a national database through a third party panel provider, M3 Global Research®. M3 Global Research® has access to over two million physicians and one million health care professionals globally for participation in both qualitative and quantitative studies. The oncologists were sampled at random and then stratified by size of institution, type of institution (academic cancer centers and community hospitals) and region within the United States to assess the following objectives: • Describe oncologist's opinions regarding the management of dermatologic toxicities, including opinions regarding the timing of rash management in relation to the initiation of treatment with Vectibix and the manner in which the rash is managed. • Describe oncologist's perceptions about the manner in which they preparing their patients for the possibility of developing dermatologic toxicities.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

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Institution

Contact details

Study institution contact

Global Development Leader Amgen Inc.

Study contact

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Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/07/2016

Actual: 15/07/2016

Study start date

Planned: 09/09/2016

Actual: 09/09/2016

Data analysis start date

Planned: 24/09/2016

Actual: 18/10/2016

Date of final study report

Planned: 18/10/2016

Actual: 18/10/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Physician perception and opinion regarding EGFR rash among mCRC patients treated with Vectibix

Data collection methods:

Primary data collection

Main study objective:

Describe oncologist’s opinions regarding the management of dermatologic toxicities, including opinions regarding the timing of rash management in relation to the initiation of treatment with Vectibix and the manner in which the rash is managed. Describe oncologist’s perceptions about the manner in which they preparing their patients for the possibility of developing dermatologic toxicities.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Survey

Study drug and medical condition

Name of medicine, other

Vetibix

Medical condition to be studied

Rash

Population studied

Short description of the study population

Oncologists (i.e.: licensed and practicing oncologist) were recruited from the M3 Global Research database who had treated at least three new or continuing metastatic colorectal cancer patients with panitumumab in the last year.

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Colorectal cancer patients

Estimated number of subjects

250

Study design details

Data analysis plan

The proportion of patients who select each answer within a survey question will be summarized and confidence intervals will be estimated as the estimated proportion ± 1.96 multiplied by the estimated standard error. We will stratify our analysis by the following variables:• Primary hospital affilation (academic/university hospital, community non-teaching hospital, and community teaching hospital).• Size of practice setting (>20 doctors, 6-20 doctors, <5 doctors, solo practice).• Number of new or continuing metastatic colorectal cancer patients the oncologist personally treated (stratify at the median number of patients reported by the participating oncologists).

Documents

Study results

20160258_ORSR Final_Abstract.pdf(74.49 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Physician survey

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown