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

First published: 26/04/2017
Last updated: 02/07/2024





Administrative details

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



Contact details

Study institution contact

Global Development Leader Amgen Inc. medinfo@amgen.com

Study contact

medinfo@amgen.com

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

Medicinal product name, 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 \pm 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

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025.

The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

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