Medical Records Review to Describe the Patterns of KRAS Testing and Vectibix Use in Europe (20101120)

First published: 11/02/2014

Last updated: 02/07/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/20214

EU PAS number

EUPAS5681

Study ID

20214

DARWIN EU® study

No

Study countries

☐ Belgium

- [ ] Czechia
- [ ] Denmark
- [ ] France
- [ ] Germany
- [ ] Italy
- [ ] Netherlands
- [ ] Spain
- [ ] Sweden

Study description

This non-interventional cross-sectional medical record review study will assess the prevalence of KRAS testing and the impact of the KRAS test result on patterns of Vectibix use in patients with metastatic colorectal cancer (mCRC) treated with Vectibix in selected European countries over 3 rounds. As the optimal use of Vectibix also requires accurate KRAS mutation testing, this study will also assess data from the laboratory that performed the KRAS test. The study will also monitor changes in the pattern of Vectibix treatment between the different rounds of the study.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

- [ ] United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Contact details

Study institution contact

Global Development Leader Amgen, Inc

Study contact

medinfo@amgen.com

Primary lead investigator

Global Development Leader Amgen, Inc

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 15/09/2011

Study start date

Actual: 19/09/2012

Data analysis start date

Actual: 12/09/2013

Date of interim report, if expected
Planned: 05/05/2014

Actual: 30/06/2014

Date of final study report
Planned: 26/11/2015

Actual: 23/11/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

Vectibix_20101120_Protocol_11Feb14.pdf(312.98 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Other

Study topic, other:

Diagnostic procedure - KRAS testing

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Other

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

Describe patterns of KRAS biomarker testing prior to initiating treatment

Data collection methods:

Secondary use of data

Main study objective:

This non-interventional cross-sectional medical record review study will assess the prevalence of KRAS testing and the impact of the KRAS test result on patterns of Vectibix use in patients with metastatic colorectal cancer (mCRC) treated with Vectibix over 3 rounds. The study will also monitor changes in the pattern of Vectibix treatment between the different rounds of the study.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Name of medicine

VECTIBIX

Medical condition to be studied

Colorectal cancer metastatic

Population studied

Short description of the study population

Patients with metastatic colorectal cancer (mCRC) treated with Vectibix following the changes of label about the risk of Vectibix use in mCRC patients with mutant KRAS tumors in selected European countries.
Patients who had received Vectibix for the treatment of mCRC during the 6-month period prior to the time when medical records were obtained, not have been in any experimental clinical trial at time of receiving Vectibix, and not have participated in this study, in an earlier round were included.

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

450

Study design details

Outcomes

The prevalence of KRAS testing and impact of the KRAS test results on patterns of Vectibix use in patients with metastatic colorectal cancer (mCRC) treated with Vectibix Timeframe: 3 Years, The proportion of oncologists who participate in the study. The proportion of oncologists who conduct a KRAS test prior to initiating Vectibix treatment. The proportion of labs that are part of an European Society of Pathology Quality Assurance scheme. The proportion of labs that use a validated KRAS testing method. To assess the change in pattern of Vectibix administation over the 3 rounds.

Data analysis plan

Analysis will be conducted on 3 levels - patient level, oncologist level and laboratory level. Descriptive statistics will be calculated at each level.

Documents

Study results

Observational Research Study Report 20101120 - Abstract.pdf(35.72 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Cross-sectional medical chart review

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