POWER: Real World Data of 1st line panitumumab treatment in combination with chemotherapy in non resectable wild type (WT) RAS metastatic colorectal cancer (mCRC) subjects in Austria, Bulgaria, Croatia, Czech Republic, Hungary, Poland, Slovenia, Romania, Russia, Greece an Observational Ambidirectional Study (20170734)

First published: 14/11/2018

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS26499

Study ID

48889

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Bulgaria
- [ ] Croatia
- [ ] Greece
- [ ] Hungary
- [ ] Poland
- [ ] Romania
- [ ] Russian Federation
- [ ] Slovenia

Study description

To obtain characteristics of subjects with WT RAS non resectable mCRC receiving panitumumab in combination with chemotherapy as a 1st line treatment, and to describe the patterns of treatment, including 1st and 2nd line therapies

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

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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: 01/05/2018

Actual: 01/05/2018

Study start date

Planned: 16/11/2018

Actual: 20/11/2018

Data analysis start date
Planned: 15/03/2022

Actual: 22/11/2021

Date of final study report
Planned: 22/11/2022

Actual: 24/08/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

20170734_01.02.06 Public Redacted Protocol Ver 1.0 2019-04-29 English.pdf
(1.3 MB)

20170734_01.02.06 Public Redacted Protocol Ver 1.0 2018-08-08 English_2.pdf
(389.81 KB)

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 topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

To obtain characteristics of subjects with WT RAS non resectable mCRC receiving panitumumab in combination with chemotherapy as a 1 st line treatment, and to describe the patterns of treatment, including 1 st and 2nd line therapies.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Multicentre, ambidirectional (retrospective-prospective), observational study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L01XC08) panitumumab

panitumumab

Medical condition to be studied

Colorectal cancer metastatic

Population studied

Short description of the study population

The study involved patients aged 18 years or older with non-resectable wild type (WT) RAS metastatic colorectal cancer (mCRC) receiving panitumumab in combination with chemotherapy as first-line treatment identified from European countries, including Austria, Bulgaria, Croatia, Czech Republic, Hungary, Poland, Slovenia, Romania, and Russia.

Inclusion criteria:

• Subject who received first infusion of panitumumab in combination with chemotherapy as 1st line treatment between 1 and 12 months before enrolment and who continues treatment with panitumumab in combination with chemotherapy at the time of enrolment

• Subject with a record of WT RAS CRC diagnosis as per standard clinical practice

• Subject with metastatic carcinoma of the colon or rectum with at least one metastatic site recorded

• Subject with initially non resectable mCRC at the start of panitumumab plus chemotherapy treatment

• Subject who was diagnosed with a tumour, assessed by CT/MRI etc. prior to panitumumab plus chemotherapy initiation

• Histologically or cytologically confirmed carcinoma of the colon or rectum as the primary site
• Subject ≥ 18 years of age on the date of enrolment
• Subjects whose care will be managed primarily by the enrolling physician and/or all records will be available from initiation of 1st line panitumumab plus chemotherapy treatment to end of safety follow up
• Subject or subject’s legally acceptable representative has provided informed consent if applicable per local regulations

Exclusion criteria:
• Subject with proven brain metastasis
• Subject with mCRC as a secondary malignancy
• Ongoing or planned concurrent participation in any interventional clinical trial

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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

Metastatic colorectal cancer patients

Estimated number of subjects

400

Study design details

Outcomes

The following data will be collected:demographics: age, sex, targeted medical history: type of primary tumour, date of diagnosis, site of primary tumour: rectum vs colon, right vs left colon, surgical procedures, lymph nodes: number and involvement, TNM stage, adjuvant chemotherapy, including regimen, sites, Response to 1st line treatment Safety assessments: ADR reports Prophylaxis treatment for skin toxicity Questionnaire FACT-EGFRI-18 if permitted in a country per local regulations.

Data analysis plan

The baseline data will be summarized using descriptive statistics for subjects with mCRC who received panitumumab in combination with chemotherapy as 1st line treatment according to the type of chemotherapy received. The data will be summarized for the total study population divided by the type of chemotherapy received: FOLFOX, FOLFIRI and others. The data will be summarized for the total study population and per country. Counts and percentages will be provided. Continuous outcomes will be summarized by the number of non-missing values, mean, standard deviation, median, lower and upper quartiles and minimum and maximum values. Time to event data alalysis using Kaplan Meier estimator. The eCRFs will be designed to minimise missing data and to optimise the integrity of collected data. Subjects’ records will not be excluded because of missing data and missing data will not be inputted. For categorical variables, missing responses will be shown as a separate category in the analysis.

Documents

Study results

20170734_ORSR_Abstract_Redacted.pdf (90.84 KB)

20170734_ORSR_Redacted.pdf (343.88 KB)

Data management

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)

Other

Data sources (types), other

Prospective patient-based data collection, Retrospective Patient 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

No