Canadian Retrospective Observational Study of MVASI in metastatic Colorectal Cancer (20180360)

First published: 17/04/2020

Last updated: 20/04/2023

Study Finalised

Administrative details

EU PAS number

EUPAS34590

Study ID

103370

DARWIN EU® study

No

Study countries

Canada

Study description

This retrospective observational chart review will describe the safety and effectiveness of treatment with MVASI in patients with metastatic Colorectal Cancer (mCRC) in Canada. The study will include adult patients, with confirmed histological or cytological adenocarcinoma of rectum or colon, stage 4, previously untreated, who receive MVASI as a part of their initial (first line) treatment for mCRC. The Data Collection will include data from the patient's first dose of MVASI (the index date) until the date of the chart review. In addition, patients will have a look-back period including a 6-month look-back for patient demographics and baseline data, and a 5-year look back for prior adjuvant treatment and diagnosis of CRC

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 27/03/2026

Institution

Multiple centres: 12 centres are involved in the study

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: 11/09/2018

Actual: 11/09/2018

Study start date

Planned: 20/03/2021

Actual: 16/03/2021

Data analysis start date

Planned: 10/11/2022

Actual: 10/11/2022

Date of interim report, if expected

Planned: 31/10/2021

Date of final study report

Planned: 14/04/2023

Actual: 06/04/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen Inc.

Study protocol

EUPAS34590-35092.pdf (454.21 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 type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To describe the safety of MVASI treatment by assessing the frequency of Events of Interest (EOIs), in first-line mCRC patients in Canada

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective chart review

Study drug and medical condition

Medicinal product name

MVASI

Medical condition to be studied

Colorectal cancer metastatic

Population studied

Short description of the study population

The study population included patients aged 18 years or older diagnosed with metastatic colorectal cancer treated with MVASI in Canada.

Inclusion criteria:

1. Adult patients ≥ 18 years of age at the Index date (first dose of MVASI)
2. Metastatic CRC ie, confirmed histological or cytological adenocarcinoma of rectum or colon, stage 4
3. Previously untreated patients who receive MVASI as a part of their initial (first line) treatment for metastatic CRC
4. Patient has received at least 1 cycle of MVASI treatment as a part of their initial (first line) treatment for metastatic CRC
5. Index date (first dose of MVASI) is at least 1 month prior to chart review date

Exclusion Criteria:

1. Patient received an investigational product or participated in an investigational device or drug study at any time between 90 days pre-index date to 30 days post-last dose of MVASI
2. Patient previously treated with bevacizumab for metastatic CRC, prior to Index Date (first dose of MVASI)
3. Patient is pregnant at any time during treatment with MVASI

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

300

Study design details

Outcomes

• Infusion reactions • Thromboembolic events • Gastrointestinal (GI) perforations • Hypertension • Hemorrhages • Wound-healing complications • Proteinuria • Ovarian Failure, Objective Response (RECIST criteria), Disease progression (if applicable)

Data analysis plan

The analysis is entirely descriptive in nature with no hypothesis testing. Frequency estimation for each of the EOIs will be based on the number of patients who experience the events (at least one event per patient) divided by the total number of patients under observation. A frequency estimate for each EOI will also be provided by treatment cycle. Confidence intervals, 2-sided 95% will be provided. An additional frequency estimate of patients experiencing at

least one instance of each EOI adjusted for duration of observation will also be provided

Documents

Study results

20180360 ORSR_Redacted.pdf (162.4 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)

Other

Data sources (types), other

Hospital retrospective 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