A Real World Evidence prospective cohort study in the management of metastatic colorectal cancer: a clinical and patient perspective (PROMETCO)

First published: 02/03/2020

Last updated: 27/05/2025

Study Finalised

Administrative details

EU PAS number

EUPAS33865

Study ID

40302

DARWIN EU® study

No

Study countries

- [ ] Argentina
- [ ] Austria
- [ ] Belgium

- [ ] Croatia
- [ ] Czechia
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Ireland
- [ ] Italy
- [ ] Netherlands
- [ ] Portugal
- [ ] Slovenia
- [ ] Spain
- [ ] Sweden
- [ ] Switzerland
- [ ] United Kingdom

Study description

This is an observational study to describe the following for mCRC patients in a real world setting:

- Overall survival
- Treatment patterns for mCRC throughout the continuum of care

Effectiveness/safety of treatments

- Reasons for therapy discontinuations and choice of subsequent treatment
- Adherence to National and European Society for Medical Oncology (ESMO) Guidelines
- Healthcare resource utilization
- Patient reported outcomes

Study status

Finalised

Research institutions and networks

Institutions

University Medical Center Utrecht (UMCU)

Netherlands

First published: 24/11/2021

Last updated: 22/02/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility | ENCePP partner

Contact details

Study institution contact

Alice Vermeire alice.vermeire@servier.com

Study contact

alice.vermeire@servier.com

Primary lead investigator

Miriam Koopman

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 23/07/2018

Study start date
Actual: 08/03/2019

Date of final study report
Planned: 30/09/2024

Actual: 21/11/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Servier

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

Other study registration identification numbers and links

ClinicalTrials.gov Identifier:

NCT03935763,https://clinicaltrials.gov/ct2/show/NCT03935763?term=PROMETCO&draw=

Methodological aspects

Study type

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Other

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

Overall survival in real world setting

Data collection methods:

Primary data collection

Study design:

This was a prospective, observational, non-interventional, international multi-center, cohort study designed to collect data on patients with mCRC after two disease progressions since diagnosis of first metastasis that led to systemic treatment.

Main study objective:

To describe the following for mCRC patients in a real world setting:

- Overall survival
- Treatment patterns for mCRC throughout the continuum of care
- Effectiveness/safety of treatments
- Reasons for therapy discontinuations and choice of subsequent treatment
- Adherence to National and European Guidelines
- Healthcare resource utilization
- Patient reported outcomes

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Colorectal cancer metastatic

Population studied

Short description of the study population

The target population was adults with mCRC who are eligible and willing to receive subsequent
treatment, having had two prior disease progressions since diagnosis of first metastasis.

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)

Estimated number of subjects

1000

Study design details

Setting

The study was conducted in 18 countries. Investigators at academic or community based medical sites in the selected countries of interest that were experienced in the treatment and management of CRC and in conducting observational studies were approached for potential participation in the study.

Data analysis plan

descriptive statistics

Summary results

This large real world study helped define the current landscape of mCRC patients and therapy, and provided both clinical information and patient reported outcomes for a robust and complete profile of global mCRC management.

Documents

Study report

DIM-95005-001_PROMETCO_CSR Version 1.0_Abstract.pdf(498.51 KB)

Data management

Data sources

Data sources (types)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prospective patient-based data collection

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