ProSpective MultIcenter ObservationaL Study on the Quality of Life of mCRC RAS Wild-type Patients Receiving Anti-EGFR MAbs + FOLFOX or FOLFIRI as 1st Line of Treatment (20140383)

First published: 11/02/2022

Last updated: 02/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS44300

Study ID

48557

DARWIN EU® study

No

Study countries

☐ Italy

Study description

This is a national, multicentric, prospective, observational trial to assess the impact of the treatment with FOLFOX or FOLFIRI plus anti-epidermal growth factor (EGFR) monoclonal antibodies (MAbs) on patients' health related quality of life (HRQoL), as measured by means of the EORTC – QLQC30 questionnaire. It will include adult patients with rat sarcoma virus (RAS) wild-type metastatic colorectal cancer who are candidates to receive first-line FOLFOX or FOLFIRI + anti-EGFR MAb as per clinical practice in around 33 Italian centers. Each physician will see their patients within the context of routine visits, without any special visit being organized for the purposes of the study. EORTC QLQ-C30 and Dermatology Life Quality Index (DLQI) questionnaires will be completed by the patients at baseline, at the first day of every other cycle (every 2 weeks) thereafter, and "End of Study Visit" (within 28 days from the end of treatment with anti-EGFR or withdrawal from study for any reason).

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

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Institution

Multiple centres: 33 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

Actual: 10/11/2014

Study start date

Planned: 30/12/2015

Actual: 30/12/2015

Data analysis start date

Planned: 13/08/2021

Actual: 13/08/2021

Date of final study report

Planned: 30/12/2021

Actual: 08/08/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

Protocol-Published Original panitumumab 20140383.pdf(742.96 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:

Assessment of risk minimisation measure implementation or effectiveness

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

Assess the impact of the treatment with FOLFOX or FOLFIRI plus anti-EGFR MAbs on patients' health related quality of life (HRQoL), as measured by means of the EORTC – QLQC30 questionnaire

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

National, multicentric, prospective, observational trial

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

PANITUMUMAB

CETUXIMAB

FLUOROURACIL

OXALIPLATIN

LEVOLEUCOVORIN

IRINOTECAN

Medical condition to be studied

Colorectal cancer

Additional medical condition(s)

Metastatic colorectal cancer RAS wild-type

Population studied

Short description of the study population

Patients aged 18 years or older diagnosed with rat sarcoma virus (RAS) wild-type metastatic colorectal cancer receiving FOLFOX or FOLFIRI + anti-EGFR MAb as the first line treatment under routine clinical practice in around 33 Italian oncology centers between November 2015 and December 2019.

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

300

Study design details

Outcomes

EORTC – QLQC30 questionnaire scores, Impact of dermatological adverse events during the treatment on patients’ skin satisfaction as measured by DLQI * Tolerability of treatments*Adherence to treatment: dose delays, dose reductions, number of administered cycles, average relative dose intensity of every drug* Management of dermatological adverse events * Effect on skin-related QoL of preemptive vs reactive treatment of skin toxicities

Data analysis plan

The absolute frequency and the percentage for the qualitative variables will be calculated, the standard deviation, the median, the minimum and the maximum will be used to summarize the quantitative variables. EORTC QLQ-C30 scores will be presented at baseline and at each time point, by treatment group, scores will be presented as a percentage of the scores reported as reference, comparisons of mean change from baseline to last study visit in quality of life scores between treatment groups will be made using a t-test, and differences in mean from baseline and last time point will be assessed with a paired t-test. The total DLQI score will be presented with statistics at baseline and at each time point. The mean change from baseline in DLQI score at the last study visit

will be compared between treatment groups using a t-test.

Documents

Study results

20140383_CSR _Synopsis_Redacted.pdf(197.78 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

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