

CONCERT - Cohort of patients with metastatic colorectal cancer initiating a chemotherapy in combination with Avastin®

Head :Roche Medical data center

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General

Identification

Detailed name	Cohort of patients with metastatic colorectal cancer initiating a chemotherapy in combination with Avastin®
Sign or acronym	CONCERT
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	ML21696

General Aspects

Medical area	Cancer research Gastroenterology et hepatology
Study in connection with Covid-19	No
Pathology (details)	Metastatic colorectal cancer
Health determinants	Medicine
Keywords	bevacizumab

Scientific investigator(s) (Contact)

Name of the director	Roche Medical data center
Address	4 cours de l'Île Seguin
Email	data_sharing.france@roche.com
Organization	Roche SAS

Collaborations

Participation in projects, networks and consortia	No
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Funding

Funding status Private

Governance of the database

Sponsor(s) or organisation(s) responsible Roche SAS

Organisation status Private

Presence of scientific or steering committees Yes

Additional contact

Main features

Type of database

Type of database Study databases

Study databases (details) Longitudinal study (except cohorts)

Database recruitment is carried out by an intermediary A selection of health care professionals

Database recruitment is made on the basis of: Medication(s) taken

Database recruitment is carried out as part of an interventional study No

Database objective

Main objective Primary Objective: To assess in real life the Progression-Free Survival at a maximum of 36 months follow-up, in patients suffering from metastatic colorectal cancer and initiating a treatment with Avastin® combined with chemotherapy.
Secondary Objectives:
- To describe characteristics of patients treated with Avastin®
- To describe the use of Avastin® over the study period
- To assess the overall survival of patients treated with Avastin®
- To describe the Avastin® safety profile (serious adverse events and/or unexpected related to Avastin®, and/or adverse events of special interest)

- To describe the quality of life of patients treated with Avastin®.

Exploratory Objective:

A search for the prognostic factors of PFS and OS was performed using a Cox model in patients treated with 1st line of chemotherapy (overall and in the subgroup of patients with synchronous metastases). These factors were determined from the characteristics of patients at inclusion.

Inclusion criteria

Inclusion criteria:

- Adult patient (aged ≥ 18 years)
- Patient suffering from metastatic colic or rectal carcinoma for which the physician decided to start a treatment with Avastin® combined with chemotherapy, at the inclusion time
- Patient who received about the study both oral and written information and who did not object to his/her personal data being processed

Exclusion criteria:

- Participation in a clinical trial designed to assess a cytotoxic anticancer treatment and/or an innovative therapy

Population type

Age

Adulthood (19 to 24 years)
Adulthood (25 to 44 years)
Adulthood (45 to 64 years)
Elderly (65 to 79 years)
Great age (80 years and more)

Population covered

Sick population

Pathology

C00-C75 - Malignant neoplasms, stated or presumed to be primary, of specified sites, except of lymphoid, haematopoietic and related tissue

Gender

Male
Woman

Geography area

National

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)

2008

Date of last collection (YYYY or MM/YYYY)

2012

Size of the database

Size of the database (number of individuals) [500-1000[individuals

Details of the number of individuals 765

Data

Database activity Data collection completed

Type of data collected Clinical data
Declarative data

Clinical data (detail) Medical registration

Details of collected clinical data Type of data collected : validation of selection criteria, information about the study, demographic and general data, disease history, previous treatments of colorectal cancer, last available laboratory tests, treatment with Avastin® and combined chemotherapy, other treatments, first disease progression, surgery for colorectal cancer, patient reported outcomes, reason for early study withdrawal, adverse events related to Avastin®.

Declarative data (detail) Paper self-questionnaire

Presence of a biobank No

Procedures

Data collection method paper questionnaire

Classifications used CDISC like

Quality procedure(s) used GCP/GVP

Participant monitoring Yes

Monitoring procedures Monitoring by contact with the referring doctor

Followed pathology C00-C75 - Malignant neoplasms, stated or presumed to be primary, of specified sites, except of lymphoid, haematopoietic and related tissue

Links to administrative sources No

Promotion and access

Promotion

Access

Dedicated website	https://www.roche.fr/fr/innovation-recherche-medicale/data-sharing-portail-d-information-partage-des-donnees.html
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Presence of document that lists variables and coding procedures	Yes
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Access to aggregated data	Access on specific project only
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Access to individual data	Access on specific project only
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