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'Ile Seguin
Email	data_sharing.france@roche.com
Organization	Roche SAS

Collaborations

Participation in projects, networks and consortia	No

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 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
Presence of document that lists variables and coding procedures	Yes
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only