PICASSO - A Cohort Study of Patients With Metastatic Colorectal Cancer Treated With Avastin® as First-line Therapy for Liver Metastases Considered as Potentially Resectable

Head :Roche Medical data center

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General

Identification

Detailed name	A Cohort Study of Patients With Metastatic Colorectal Cancer Treated With Avastin® as First-line Therapy for Liver Metastases Considered as Potentially Resectable
Sign or acronym	PICASSO
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	ML22999

General Aspects

Medical area	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 - 92100 Boulogne-Billancourt
Email	data_sharing.france@roche.com
Organization	Roche SAS

Collaborations

Participation in projects,	No

networks and consortia

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)	Cohort study
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: evaluate the efficacy and safety of bevacizumab as first-line treatment in participants with colorectal cancer and potentially resectable liver metastases. Secondary Objectives: - To describe patients' characteristics treated with Avastin®, - To describe the subgroup of patients with unresected missing metastases, with or without surgery, - To describe criteria used to define unresectability, - To describe progression-free survival in all patients, - To describe relapse-free survival in all resected patients with no DMD,

	- To describe overall survival in all patients, - To describe histopathological response in resected patients, - To describe Avastin® treatment modalities, - To describe safety profile of Avastin®.
Inclusion criteria	Inclusion criteria: - Man or woman aged 18 years or over, - Diagnosed with a colon or rectal adenocarcinoma including exclusively liver or liver and lung metastases, - For whom a first-line treatment with Avastin® was set up by a MDC in the context of potentially resectable metastatic disease, - Who has been informed orally and in writing about the study, its objectives and modalities of implementation and who did not object that the collected data were subject to an automated processing. Exclusion criteria: - Patient considered as upfront resectable at inclusion, - Patient considered as he/she could never be resectable, - Patient already enrolled in a clinical study for cytotoxic anticancer medication and/or 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)	2010

Date of last collection (YYYY or MM/YYYY)	2015
Size of the database	
Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	218
Data	
Database activity	Data collection completed
Type of data collected	Clinical data Declarative data
Clinical data (detail)	Medical registration
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health event/mortality
Procedures	
Data collection method	eCRF
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