CASSIOPEE - Non Interventional Study Evaluating Efficacy and Safety in a Cohort of Elderly Patients of First Line Therapy With Avastin ® Regimen for Metastatic Colorectal Cancer

Head :Roche Medical data center

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General

Identification

Detailed name	Non Interventional Study Evaluating Efficacy and Safety in a Cohort of Elderly Patients of First Line Therapy With Avastin ® Regimen for Metastatic Colorectal Cancer
Sign or acronym	CASSIOPEE
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	ML27829

General Aspects

Medical area	Cancer research Gastroenterology et hepatology
Study in connection with Covid-19	No
Pathology (details)	Onco digestive, 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, 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)	Cohort study
Database recruitment is carried out by an intermediary	A selection of health institutions and services
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: Progression-free survival in patients aged >= 75 years with metastatic colorectal cancer initiating first line treatment with Avastin® Secondary Objectives: - To describe the demographic, clinical and nutritional profiles of the patients and their living conditions and degree of autonomy; - To describe the change in autonomy criteria; - To describe the OS; - To describe Avastin® dosage and regimen; - To describe the safety profile of Avastin®.
Inclusion criteria	Inclusion criteria:

	- Adult patient aged >= 75 years, - With metastatic adenocarcinoma of the colon or rectum, - For whom it has been decided to initiate first line treatment with Avastin®, concomitant to or no more than 2 months after the start of first line chemotherapy - Having received oral and written information about the study objectives and methods and having raised no objections to computer processing of the data in the medical record (indirectly named data). Exclusion criteria: - Patient previously treated with Avastin®. - Patient already participating in a clinical trial evaluating a cytotoxic anticancer therapy and/or an investigational new drug.
Population type	
Age	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)	2012
Date of last collection (YYYY or MM/YYYY)	2016
Size of the database	
Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	402
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
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