

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

Last update : 11/26/2021 | Version : 1 | ID : 74086

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 made on the basis of:	Medication(s) taken
---	---------------------

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

Database objective

Main objective	<p>Primary Objective: Progression-free survival in patients aged ≥ 75 years with metastatic colorectal cancer initiating first line treatment with Avastin®</p> <p>Secondary Objectives:</p> <ul style="list-style-type: none">- 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