

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®
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Sign or acronym	CONCERT
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CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	ML21696
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General Aspects

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

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

Participation in projects, networks and consortia	No
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Funding

Funding status	Private
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Governance of the database

Sponsor(s) or organisation(s) responsible	Roche SAS
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Organisation status	Private
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Presence of scientific or steering committees	Yes
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Additional contact

Main features

Type of database

Type of database	Study databases
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Study databases (details)	Longitudinal study (except cohorts)
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Database recruitment is carried out by an intermediary	A selection of health care professionals
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Database recruitment is made on the basis of:	Medication(s) taken
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Database recruitment is carried out as part of an interventional study	No
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Database objective

Main objective	<p>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.</p> <p>Secondary Objectives:</p> <ul style="list-style-type: none">- 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)
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- 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	<p>Inclusion criteria:</p> <ul style="list-style-type: none">- 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 <p>Exclusion criteria:</p> <ul style="list-style-type: none">- Participation in a clinical trial designed to assess a cytotoxic anticancer treatment and/or an innovative therapy
Population type	
Age	<p>Adulthood (19 to 24 years)</p> <p>Adulthood (25 to 44 years)</p> <p>Adulthood (45 to 64 years)</p> <p>Elderly (65 to 79 years)</p> <p>Great age (80 years and more)</p>
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	<p>Male</p> <p>Woman</p>
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
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Details of the number of individuals	765
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Data

Database activity	Data collection completed
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Type of data collected	Clinical data Declarative data
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Clinical data (detail)	Medical registration
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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®.
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Declarative data (detail)	Paper self-questionnaire
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Presence of a biobank	No
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Procedures

Data collection method	paper questionnaire
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Classifications used	CDISC like
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Quality procedure(s) used	GCP/GVP
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Participant monitoring	Yes
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Monitoring procedures	Monitoring by contact with the referring doctor
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Followed pathology	C00-C75 - Malignant neoplasms, stated or presumed to be primary, of specified sites, except of lymphoid, haematopoietic and related tissue
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Links to administrative sources	No
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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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