Flash-KRAS - Retrospective observational study taking an inventory of the KRAS test in 2011 in patients with metastatic colorectal cancer having recently started a first-line treatment

Head :Dr ARTRU Pascal, Department of Hepato-Gastroenterology and Digestive Oncology, Hôpital Jean Mermoz, Lyon
Pr DUCREUX Michel, Gastroenterology Unit, IGR, Villejuif
Dr GUIU Michel, Department of Anatomy and Pathology, Perpignan
Dr LAURENT-PUIG Pierre, Department of Biochemistry, HEGP, Paris
Dr LIEVRE Astrid, Department of Hepato-Gastroenterology and Digestive Oncology, Hôpital Ambroise Paré, Boulogne Billancourt
Pr MERLIN Jean-Louis, Tumour Biology Unit, Centre Alexis Vautrin, Nancy
Pr SABOURIN Jean-Christophe, Department of Anatomy and Pathological Cytology, CHU Ch.Nicolle, Rouen
Dr VIGUIER Jerôme, Department of Gastroenterology and Hepatology, Hôpital Trousseau, Tours

Last update : 10/19/2017 | Version : 1 | ID : 73327

General

Identification

Detailed name	Retrospective observational study taking an inventory of the KRAS test in 2011 in patients with metastatic colorectal cancer having recently started a first-line treatment
Sign or acronym	Flash-KRAS
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL n°1474442

General Aspects

Medical area	Anatomy - Cytology Biology Cancer research
Pathology (details)	Colorectal cancer
Health determinants	Healthcare system and access to health care services
Keywords	Flash-KRAS, Colorectal cancer

Scientific investigator(s) (Contact)

Name of the director	Dr ARTRU

Surname	Pascal
Unit	Department of Hepato-Gastroenterology and Digestive Oncology, Hôpital Jean Mermoz, Lyon
Name of the director	Pr DUCREUX
Surname	Michel
Unit	Gastroenterology Unit, IGR, Villejuif
Name of the director	Dr GUIU
Surname	Michel
Unit	Department of Anatomy and Pathology, Perpignan
Name of the director	Dr LAURENT-PUIG
Surname	Pierre
Unit	Department of Biochemistry, HEGP, Paris
Name of the director	Dr LIEVRE
Surname	Astrid
Unit	Department of Hepato-Gastroenterology and Digestive Oncology, Hôpital Ambroise Paré, Boulogne Billancourt
Name of the director	Pr MERLIN
Surname	Jean-Louis
Unit	Tumour Biology Unit, Centre Alexis Vautrin, Nancy
Name of the director	Pr SABOURIN
Surname	Jean-Christophe
Unit	Department of Anatomy and Pathological Cytology, CHU Ch.Nicolle, Rouen
Name of the director	Dr VIGUIER
Surname	Jerôme
Unit	Department of Gastroenterology and Hepatology, Hôpital Trousseau, Tours

Collaborations

Participation in projects, networks and consortia	No
Funding	
Funding status	Private
Details	Merck
Governance of the database	
Sponsor(s) or organisation(s) responsible	Merck
Organisation status	Private
Presence of scientific or steering committees	Yes
Labelling and database evaluation	Scientific committee
Additional contact	
Main features	
Type of database	
Type of database	Study databases
Database recruitment is carried out by an intermediary	A selection of health care professionals A selection of health institutions and services
Database recruitment is is made on the basis of:	Another treatment or procedure
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	Retrospective, non-interventional pharmaco-epidemiological study. This study does not change the usual practices of the physician with respect to their patient.
Database objective	
Main objective	Evaluate the KRAS test prescription rate in patients starting a first-line treatment for metastatic colorectal cancer. Secondary objectives:

	- Describe the potential reasons for not prescribing this test - Describe and analyse the clinical characteristics of patients and treatments planned and received in first-line metastatic treatment - Describe and analyse the time frame for obtaining the result of the KRAS test and the channel (who makes the request and when) and the therapeutic attitude adopted during this period - Analyse the impact of the availability of the KRAS test and its result on the therapeutic choice of the physician - Describe the technic used for the analysis, the type of mutation (if available) and the method for reporting the results to the clinicians (report of the results)
Inclusion criteria	Each participating centre had to select the exhaustiveness of the patients seen in consultation during the study period, meeting all of the following criteria: - Patients aged 18 years or older, - Patients with histologically proven metastatic colorectal cancer, - Patients for whom a metastatic first-line treatment was initiated between 01/01/2011 and 27/03/2011, - Patients seen in consultation during the official 2-week study selection period.
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	II - Neoplasms
Gender	Male Woman
Geography area	National
Detail of the geography area	France
Data collection	
Dates	
Date of first collection (YYYY or	28/03/2011

MM/YYYY)	
Date of last collection (YYYY or MM/YYYY)	08/04/2011
Size of the database	
Size of the database (number of individuals)	[500-1000[individuals
Details of the number of individuals	n=538 patients (160 centres)
Data	
Database activity	Data collection completed
Type of data collected	Clinical data Declarative data Biological data
Clinical data (detail)	Direct physical measures
Details of collected clinical data	History of early colorectal cancer; First line metastatic treatment; Prescription of KRAS biomarker genotyping; impact of the result on therapeutic management
Declarative data (detail)	Paper self-questionnaire
Details of collected declarative data	Demographic characteristics of the physician, data related to the medical practice, size of the town of the medical practice, physician's thesis year / Patient's demographics data
Biological data (detail)	Waiting period for KRAS test result; genotyping report
Presence of a biobank	No
Health parameters studied	Health care consumption and services
Procedures	
Data collection method	Medical records of patients seen during the study period retrospectively and using a paper questionnaire. Anonymised copy of the molecular biology report
Participant monitoring	No
Followed pathology	

Links to administrative sources	No

Promotion and access

Promotion

Link to the document	Lievre A et al. EJC Juin 2013.pdf
Link to the document	Poster KRAS ESMO version finale.pdf
Description	ESMO 2012
Link to the document	poster Flash-KRAS JFHOD.pdf
Description	JFHOD 2012

Access

Presence of document that lists variables and coding procedures	No
Terms of data access (charter for data provision, format of data, availability delay)	Access terms and conditions are being defined Contact: juliette.longin@merckgroup.com
Access to aggregated data	Access on specific project only
Access to individual data	No access