

Flash-RAS - Observational, retrospective study exploring RAS mutation tests practices in patients with metastatic colorectal cancer in 2014

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Last update : 06/09/2016 | Version : 1 | ID : 73329

General	
Identification	
Detailed name	Observational, retrospective study exploring RAS mutation tests practices in patients with metastatic colorectal cancer in 2014
Sign or acronym	Flash-RAS
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL n°1748157
General Aspects	
Medical area	Anatomy - Cytology Biology Cancer research
Pathology (details)	Colorectal cancer
Health determinants	Healthcare system and access to health care services
Keywords	RAS mutation tests, Colorectal cancer
Scientific investigator(s) (Contact)	
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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 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.	A list of hospital physicians (oncologists and gastroenterologists) treating patients with metastatic colorectal cancer in France, issued from the program of Medicalisation of data system (PMSI) and/or having taken part in the Flash-KRAS Study in 2011, were invited to participate in the study by letter or by telephone.
Database objective	
Main objective	<p>To assess the RAS (KRAS and NRAS exons 2,3 and 4) mutation screening test request and realisation rates in patients with a recent diagnosis of metastatic colorectal cancer.</p> <p>Secondary objectives:</p> <ul style="list-style-type: none"> - To describe changes in the KRAS (exon 2) mutation test request rate between 2011 and 2014; - To describe the reasons for requesting/not requesting and performing/not performing these tests as a function of physician and patient profiles - To describe and to analyse the impact of KRAS (exons 2,3 and 4) and NRAS (exons 2.3 and 4) results, the anatomopathology department availability to provide the tests, and the BRAF result, on therapeutic decision-making or changes in ongoing treatment;

- To describe and analyse clinical characteristics of patients and treatments planned and received as first-line therapy of metastatic disease;
- To describe the laboratory test method, the type of mutation request (if available) and the method and route by which the result was communicated to the physicians (result report);
- To describe and to analyse the time to receipt the KRAS and NRAS results, the process (who ordered the test and when) and the therapeutic approach chosen during this period

Inclusion criteria	<p>To obtain the best possible representativeness while limiting bias, the physician had to screen consecutive patients followed for metastatic colorectal cancer and who had to satisfy the following criteria:</p> <ul style="list-style-type: none"> - patients 18 years of age or older, - patients with metastatic colorectal cancer histologically-confirmed after march 2014 (date the NRAS tests become available in French centers), - patients seen by the physician between June 15th , 2014 and September 30th, 2014 who have already started first-line treatment, during that time interval, for mCRC - patients in whom first-line therapy of metastatic disease had been already initiated between March 1st, 2014 and June 30th, 2014 - patients seen in a routine visit during the official 15-week screening period of the study
Population type	
Age	<p>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)</p>
Population covered	Sick population
Gender	<p>Male Woman</p>
Geography area	National
Detail of the geography area	France
Data collection	
Dates	
Date of first collection (YYYY or	15/06/2014

MM/YYYY)

Date of last collection (YYYY or MM/YYYY) 30/09/2014

Size of the database

Size of the database (number of individuals) < 500 individuals

Details of the number of individuals N= 375 patients, included by 104 physicians

Data

Database activity Data collection completed

Type of data collected Clinical data
Declarative data
Biological data

Clinical data (detail) Medical registration

Details of collected clinical data History of primary colorectal cancer; first-line therapy of metastatic disease; request for KRAS marker genotyping; impact of result on therapeutic management

Declarative data (detail) Paper self-questionnaire

Details of collected declarative data Physician's demographic characteristics; data related to his/her practice; size of community of practice; date the KRAS test became available in the pathology/department center; demographic data on patients

Biological data (detail) Waiting period for test result; genotyping test report

Presence of a biobank No

Health parameters studied Health care consumption and services

Procedures

Data collection method Data collected were obtained from the medical notes of patients seen at a visit during the study period (data already recorded), retrospectively with a paper questionnaire and the copy of the molecular biology report from which all reference to the patient by name had been removed to be anonymous

Participant monitoring	No
Links to administrative sources	No
Promotion and access	
Promotion	
Link to the document	FLASH RAS poster Carrefour patho 2015 VF.pdf
Description	Carrefour pathologie, Novembre 2015
Link to the document	FLASH RAS poster ISPOR 2015 VF.pdf
Description	ISPOR, Novembre 2015
Link to the document	poster_FlashRAS_120x80cm_HD_std - JFHOD 2015- VF.pdf
Description	JFHOD 2015
Link to the document	FLASH RAS communication orale PEP7 VF.pptx
Description	Communication orale, 7° colloque PEP 2015
Link to the document	Poster ESMO.pdf
Description	ESMO, Septembre 2015
Access	
Presence of document that lists variables and coding procedures	No
Terms of data access (charter for data provision, format of data, availability delay)	Methods of access are currently being defined. Contact: juliette.longin@merckgroup.com
Access to aggregated data	Access on specific project only
Access to individual data	No access