EREBUS - Evaluation of targeted therapies in patients receiving first-line treatment for metastatic colorectal cancer: cetuximab in the real-life conditions of use

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General

Identification

Detailed name	Evaluation of targeted therapies in patients receiving first-line treatment for metastatic colorectal cancer: cetuximab in the real-life conditions of use
Sign or acronym	EREBUS
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CCTI-RS 09.206, CNIL 909177

General Aspects

Medical area	Cancer research
Health determinants	Iatrogenic
Others (details)	Metastatic colorectal cancer
Keywords	cetuximab, Erbitux®, Metastatic colorectal cancer, conditions of use, first-line, tolerance, survival, pharmacoepidemiology, cohort, Department of Pharmacology, Bordeaux

Scientific investigator(s) (Contact)

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Collaborations

Funding

Funding status	Mixed
Details	Merck Lipha Santé

Governance of the database

Sponsor(s) or organisation(s) responsible	Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen
Organisation status	Public

Additional contact

Main features

Type of database

Type of database	Study databases
Study databases (details)	Longitudinal study (except cohorts)
Database recruitment is carried out by an intermediary	A selection of health institutions and services
Database recruitment is is made	Medication(s) taken

on the basis of:	
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	Pharmacies of centres performing at least one session of chemotherapy for metastatic colorectal cancer in 2007 according to data from the PMSI (Programme de Médicalisation des Systèmes d'Information), were contacted to participate in the study. The identification of patients and prescribing physicians is performed by hospital pharmacists through nominative dispensations. A request to participate is then made to the prescribing physicians or their head of department to inform identified patients. Physicians who accepted then informed patients of the study and allowed CRAs in charge of data collection access to medical records .

Database objective

Main objective	The main objective is to evaluate the rate of secondary metastases resection at 12 months in real-life conditions of use in patients with colorectal cancer treated by Cetuximab® first line metastatic.
Inclusion criteria	Patient with metastatic colorectal cancer initiating first-line treatment with cetuximab® between 1 January 2009 and 31 December 2010, whether or not treatment is continued; Patient not previously treated by cetuximab®, including during a clinical trial or Temporary Authorisation for Use; Patient naive to palliative metastatic chemotherapyd; No neoadjuvant chemotherapy / adjuvant of primary cancer or interval between the latter and the initiation of first-line treatment with cetuximab® ?6 months (with a tolerance of 15 days); No neoadjuvant / adjuvant of chemotherapy for metastatic cancer between or interval between the latter and initiation of first-line treatment with cetuximab® ?12 months (with a tolerance of 1 month); Patient with unresectable metastases immediately before initiation of cetuximab®; Patient with non-mutated K-RAS; Patient not participating in a clinical trial or treatment conditions considered to be unaffected by the coordinating center; Patient without locoregional relapse; Patient not objecting to data collection.

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
Gender	Male Woman
Geography area	National
Detail of the geography area	Hospital pharmacists and physicians in metropolitan France

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	2010
Date of last collection (YYYY or MM/YYYY)	2012

Size of the database

Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	En cours de recrutement, 2755 patients identifiés par les pharmaciens hospitaliers, dont 1047 patients pour lesquels le médecin a accepté de participer à l'étude, dont 205 éligibles pour le suivi en 2009 - Currently being recruited, 2755 patients identified by hospital pharmacists, including 1047 patients for whom their physician agreed to participate in the study, 205 eligible for follow-up in 2009.

Data

Database activity	Data collection completed
Type of data collected	Clinical data
Clinical data (detail)	Direct physical measures
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health event/mortality

	Health care consumption and services
Care consumption (detail)	Hospitalization Medicines consumption
Procedures	
Data collection method	During the inclusion period and follow-up, coordinating centre CRAs organize visits to the hospital to collect on an e-CRF information from the medical records of included patients.
Participant monitoring	Yes
Details on monitoring of participants	The characteristics of all patients initiating treatment with Cetuximab® in 2009 are described and only patients with unresectable metastatic colorectal cancer, non-mutated K-RAS, and starting therapy with cetuximab® between 2009 and 2010 as first-line treatment are followed over a period of 12 months from the date of first cetuximab® administration. Follow-up is performed using data available in medical records.
Links to administrative sources	No
Promotion and access	
Promotion	
Link to the document	http://www.snfge.com/JFHOD2011/5645.html
Link to the document	http://www.asco.org/ASCOv2/Meetings/Abstracts?&vmview
Link to the document	http://www.snfge.com/jfhod2012/5996.html
Access	
Terms of data access (charter for data provision, format of data, availability delay)	A confidential study report will be delivered to the pharmaceutical company. The study report and scientific communications (posters, paper, ...) are validated by the study Scientific Committee. Ownership of study data is the subject of an agreement between the University of Bordeaux Segalen and the pharmaceutical company. Terms for third-party access to the database are to be defined.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only