ETNA - Field Study of innovative therapies in oncology: bevacizumab (Avastin®), an anti-angiogenic agent

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General

Identification

Detailed name	Field Study of innovative therapies in oncology: bevacizumab (Avastin®), an anti-angiogenic agent
Sign or acronym	ETNA
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CCTI-RS 06 270, CNIL 906234

General Aspects

Medical area	Cancer research
Health determinants	Iatrogenic
Keywords	Metastatic colorectal cancer, first-line, conditions of use, pharmacoepidemiology, Department of Pharmacology, bevacizumab, Avastin®, tolerance, survival, cohort, Bordeaux

Scientific investigator(s) (Contact)

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Unit	Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen
Organization	Université Bordeaux
Collaborations	
Funding	
Funding status	Mixed
Details	National Hospital Clinical Research Program (PHRC) 2005 and additional financial support from Roche SAS (unconditional support)
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	An administrative base or a register
Database recruitment is is made on the basis of:	Medication(s) taken
Database recruitment is carried	No

out as part of an interventional study	
Additional information regarding sample selection.	Patients treated for the first time by bevacizumab between 1 January 2006 and 31 December 2007 were identified from pharmacy dispensation records of the participating centres. This retrospective identification of patients through pharmacies strengthens the non-interventional aspect, as it does not affect the prescription of the drug. Prescribers in the study were to then inform patients about the collection of their personal data. Patients opposing the collection of data could express this via the physician or by by an instruction included in their medical records, and such patients were not included.
Database objective	
Main objective	The main objectives of the study were to describe the population of patients with metastatic colorectal cancer and treated in real-life with first-line bevacizumab, describe the conditions of use of this drug, evaluate the safety of treatments and effectiveness in terms of response and overall and progression free survival at 12 and 24 months follow up.
Inclusion criteria	Patient with metastatic colorectal cancer who initiated bevacizumab in first-line palliative treatment regardless of the associated cancer treatment between 1 January 2006 and 31 December 2007 (whether or not the treatment is continued); Interval between adjuvant chemotherapy for primary cancer and the initiation of bevacizumab ?6 months; Absence of chemotherapy for metastases before initiation of bevacizumab; Patient had not previously treated with bevacizumab, including during a clinical trial or Temporary Authorisation of Use; Patient with a prescribing physician or their head of department who agreed to participate in the study; Patient not participating in a clinical trial (Huriet-Sérusclat), unless it has a standard treatment (control arm) in an open-label Phase III study (bevacizumab known); Patient not objecting to the 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)	2007
Date of last collection (YYYY or MM/YYYY)	2011

Size of the database

Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	411

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	All medical data required for the study is collected on paper case report forms from medical records by CRAs trained for this study.

Participant monitoring	Yes
Details on monitoring of participants	The treatment modalities for eligible patients are collected over 24 months follow-up from the date of the first bevacizumab administration. Vital status is collected at 36 months. Patient characteristics before initiation of treatment and follow-up data are collected from information available in medical records.
Links to administrative sources	No

Promotion and access

Promotion

Link to the document	http://www.ncbi.nlm.nih.gov/pubmed/?term=%28Fourrier-Reglat+A[author]+OR+Moore+N[author]%29+AND+Etna
Description	List of publications in Pubmed

Access

Terms of data access (charter for data provision, format of data, availability delay)	Confidential study reports were submitted to the pharmaceutical company and the Bordeaux University Hospital (study sponsor). Scientific communications (posters, articles, ...) are validated by the study Steering Committee. Ownership of study data was the subject of an agreement between the University of Bordeaux Segalen, the Bordeaux University Hospital 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