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

Responsable(s) :Fourrier-Reglat Annie, Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen
Moore Nicholas, Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen

Date de modification : 07/02/2014 | Version : 3 | ID : 2907

Général

Identification

Nom détaillé	Field Study of innovative therapies in oncology: bevacizumab (Avastin®), an anti-angiogenic agent
Sigle ou acronyme	ETNA
Numéro d'enregistrement (ID-RCB ou EUDRACT, CNIL, CPP, etc.)	CCTI-RS 06 270, CNIL 906234

Thématiques générales

Domaine médical	Cancer research
Déterminants de santé	Iatrogenic
Mots-clés	Metastatic colorectal cancer, first-line, conditions of use, pharmacoepidemiology, Department of Pharmacology, bevacizumab, Avastin®, tolerance, survival, cohort, Bordeaux

Responsable(s) scientifique(s)

Nom du responsable	Fourrier-Reglat
Prénom	Annie
Adresse	Bât du Tondu - Case 41 - 146, Rue Léo Saignat - 33076 BORDEAUX Cedex
Téléphone	+ 33 (0)5 57 57 46 75
Email	annie.fourrier@pharmaco.u-bordeaux2.fr
Laboratoire	Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen
Organisme	Université Bordeaux

Nom du responsable	Moore
Prénom	Nicholas
Adresse	Bât du Tondu - Case 41 - 146, Rue Léo Saignat - 33076 BORDEAUX Cedex
Téléphone	+ 33 (0)5 57 57 46 75
Email	nicholas.moore@pharmaco.u-bordeaux2.fr
Laboratoire	Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen
Organisme	Université Bordeaux

Collaborations

Financements

Financements	Mixed
Précisions	National Hospital Clinical Research Program (PHRC) 2005 and additional financial support from Roche SAS (unconditional support)

Gouvernance de la base de données

Organisation(s) responsable(s) ou promoteur	Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen
Statut de l'organisation	Secteur Public

Contact(s) supplémentaire(s)

Caractéristiques

Type de base de données

Type de base de données	Study databases
Base de données issues d'enquêtes, précisions	Longitudinal study (except cohorts)
Origine du recrutement des participants	An administrative base or a register
Critère de sélection des participants	Medication(s) taken
Le recrutement dans la base de	No

données s'effectue dans le cadre d'une étude interventionnelle	
Informations complémentaires concernant la constitution de l'échantillon	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.
Objectif de la base de données	
Objectif principal	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.
Critères d'inclusion	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.
Type de population	
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 concernée	Sick population
Sexe	Male Woman
Champ géographique	National
Détail du champ géographique	Hospital pharmacists and physicians in metropolitan France

Collecte

Dates

Année du premier recueil	2007
Année du dernier recueil	2011

Taille de la base de données

Taille de la base de données (en nombre d'individus)	< 500 individuals
Détail du nombre d'individus	411

Données

Activité de la base	Data collection completed
Type de données recueillies	Clinical data
Données cliniques, précisions	Direct physical measures
Existence d'une biothèque	No
Paramètres de santé étudiés	Health event/morbidity Health event/mortality Health care consumption and services
Consommation de soins, précisions	Hospitalization Medicines consumption

Modalités

Mode de recueil des données	All medical data required for the study is collected on paper case report forms from medical records by CRAs trained for this study.
Suivi des participants	Yes

Détail du suivi	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.
Appariement avec des sources administratives	No

Valorisation et accès

Valorisation et accès

Lien vers le 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

Accès

Charte d'accès aux données (convention de mise à disposition, format de données et délais de mise à disposition)	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.
Accès aux données agrégées	Access on specific project only
Accès aux données individuelles	Access on specific project only