VESUVE (beta) - Velcade: study of real-life use

Head :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

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General

Identification

Detailed name	Velcade: study of real-life use
Sign or acronym	VESUVE (beta)
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CCTI-RS 05 375, CNIL 1133894

General Aspects

Medical area	Cancer research Hematology
Keywords	Multiple myeloma, Velcade®, Bortezomib, survival, conditions of use, pharmacoepidemiology, cohort, Department of Pharmacology, Bordeaux

Scientific investigator(s) (Contact)

Name of the director	Fourrier-Reglat
Surname	Annie
Address	Bât du Tondu - Case 41 - 146, Rue Léo Saignat - 33076 BORDEAUX Cedex
Phone	+ 33(0)5 57 57 46 75
Email	Annie.fourrier@pharmaco.u-bordeaux2.fr
Unit	Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen
Organization	Université Bordeaux
Name of the director	Moore

Surname	Nicholas
Address	Bât du Tondu - Case 41 - 146, Rue Léo Saignat - 33076 BORDEAUX Cedex
Phone	+ 33 (0)5 57 57 46 75
Email	nicholas.moore@u-bordeaux.fr
Unit	Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen
Organization	Université Bordeaux

Collaborations

Funding

Funding status	Mixed
Details	Laboratoire Janssen-Cilag France (soutien inconditionnel) - Janssen-Cilag France (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	A selection of health care professionals A selection of health institutions and services
Database recruitment is is made on the basis of:	Medication(s) taken
Database recruitment is carried out as part of an interventional study	No
Additional information regarding	All hospital pharmacies that purchased bortezomib

sample selection.	at the time of study implementation were contacted. Pharmacists of participating centres have, from nominative dispensation registers, identified patients who received a first prescription of bortezomib during the study period. The prescribing physicians were contacted and asked to participate in the study. Participating physcians informed patients of the study and gave access to medical records to the CRAs in charge of the data collection.
Database objective	
Main objective	The objectives are to evaluate the response and survival of patients treated by Velcade®, to describe the population of patients initiating treatment with Velcade® (socio-demographic data, previous treatments, indication), and describe the conditions of use Velcade® (dose, number and frequency of treatment cycles)
Inclusion criteria	Patients initiating Bortezomib treatment between 1 May 2004 and April 30 2006 (whether or not treatment is continued); Patient unexposed to bortezomib, including during a clinical trial or temporary use authorization; Patient followed by a hospital physician having agreed to participate in the study; Patient not participating in a clinical trial; 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	2004

MM/YYYY)	
Date of last collection (YYYY or MM/YYYY)	2006
Size of the database	
Size of the database (number of individuals)	[500-1000[individuals
Details of the number of individuals	1310 patients identified by hospital pharmacists, including 924 patients for whom their physician agreed to participate in the study, and 793 patients were eligible for follow up.
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)	Medicines consumption
Procedures	
Data collection method	CRAs have collected data on site using a standardized electronic case report forms (e-CRF). The indication for treatment with bortezomib was collected for all patients, but only those treated for multiple myeloma were followed.
Participant monitoring	Yes
Details on monitoring of participants	Patients treated for multiple myeloma are followed over three years (from the date of first administration of Velcade®) using data available in medical records.
Links to administrative sources	No
Promotion and access	
Promotion	

Link to the document	http://www.ncbi.nlm.nih.gov/pubmed/23808815
Link to the document	http://www.asco.org/ASCOv2/Meetings/Abstracts?&vmview

Access

Terms of data access (charter for data provision, format of data, availability delay)	A confidential study report was submitted to the pharmaceutical company and sent to health authorities after validation by the study Scientific Committee. Ownership of study data was 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