

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

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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

Study in connection with Covid-19 No

Health determinants Medicine

Keywords Multiple myeloma, Velcade®, Bortezomib, survival, conditions of use, pharmacoepidemiology, cohort, Department of Pharmacology, 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	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	No

out as part of an interventional study

Additional information regarding sample selection.

All hospital pharmacies that purchased bortezomib 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 physicians 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

Pathology

C81-C96 - Malignant neoplasms, stated or presumed to be primary, of lymphoid, haematopoietic and related tissue

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) 2004

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