- MELISSE

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General

Identification

Detailed name	MELISSE
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	--

General Aspects

Medical area	Cancer research
Keywords	prophylaxis, thalidomide, lenalidomide

Scientific investigator(s) (Contact)

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Surname	Anne
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Unit	LEO Pharma France
Organization	LEO Pharma

Collaborations

Funding

Funding status	Public
Details	LEO Pharma

Governance of the database

Sponsor(s) or organisation(s) responsible	Laboratoire LEO pharma
Organisation status	Private

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 on the basis of:	Medication(s) taken
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	There is no random sampling - all subjects meeting the criteria are included

Database objective

Main objective	Describe the prophylactic treatment of phlebitis in patients suffering from multiple myeloma and receiving thalidomide or lenalidomide treatment: - Describe the proportion of patients under prophylactic treatment for phlebitis; - Define the importance of low-molecular-weight heparins (LMWH), vitamin K antagonists (VKA) and aspirin, as well as the arrangements for their use in preventing phlebitis. Describe, over a period of 4 and then 8 months, the occurrence of thromboembolic and hemorrhagic events in patients with multiple myeloma who are under thalidomide or lenalidomide treatment, depending on the thromboprophylactic strategy set up upon inclusion
Inclusion criteria	Adult patient with introduction to thalidomide or lenalidomide treatment for multiple myeloma (1st, 2nd or 3rd line of chemotherapy). Non-inclusion criteria: patient participating or having participated over the previous three months in a biomedical trial on anticoagulants

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	General population
Gender	Male Woman
Geography area	National
Detail of the geography area	60 hospitals with a hemato-oncology unit, based in mainland France

Data collection

Dates	
Date of first collection (YYYY or MM/YYYY)	2008
Date of last collection (YYYY or MM/YYYY)	2011

Size of the database	
Size of the database (number of individuals)	[500-1000[individuals
Details of the number of individuals	600

Data	
Database activity	Current data collection
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	- Center questionnaire: to be completed by centers agreeing to take part in the trial.- Data collection booklet: to be completed by the participant physicians for each patient screened and each patient included
Participant monitoring	Yes
Links to administrative sources	No

Promotion and access

Promotion	
Link to the document	http://www.ncbi.nlm.nih.gov/pubmed/?term=Lamblin+A[author]+AND+Melisse
Description	List of publications in Pubmed

Access	
Terms of data access (charter for data provision, format of data, availability delay)	3 oral presentations will be given about the trial at international congresses (ASH,ISTH,EHA) Article submitted for publication
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only