

- 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)

Name of the director Lamblin

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 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	<p>Describe the prophylactic treatment of phlebitis in patients suffering from multiple myeloma and receiving thalidomide or lenalidomide treatment:</p> <ul style="list-style-type: none"> - 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. <p>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</p>
Inclusion criteria	<p>Adult patient with introduction to thalidomide or lenalidomide treatment for multiple myeloma (1st, 2nd or 3rd line of chemotherapy).</p> <p>Non-inclusion criteria: patient participating or having participated over the previous three months in a biomedical trial on anticoagulants</p>

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

Dates

Date of first collection (YYYY or MM/YYYY)	2008
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Date of last collection (YYYY or MM/YYYY)	2011
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Size of the database

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

Database activity	Current data collection
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Type of data collected	Clinical data
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Clinical data (detail)	Direct physical measures
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Presence of a biobank	No
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Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services
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Care consumption (detail)	Medicines consumption
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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
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Participant monitoring	Yes
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Links to administrative sources	No
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Promotion and access

Promotion

Link to the document	http://www.ncbi.nlm.nih.gov/pubmed/?term=Lamblin+A[author]+AND+Melisse
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Description	List of publications in Pubmed
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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
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Access to aggregated data	Access on specific project only
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Access to individual data	Access on specific project only
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