

# - 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
<b>Additional contact</b>	
<b>Main features</b>	
<b>Type of database</b>	
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
<b>Database objective</b>	
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"> <li>- Describe the proportion of patients under prophylactic treatment for phlebitis;</li> <li>- 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.</li> </ul> <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	<a href="http://www.ncbi.nlm.nih.gov/pubmed/?term=Lamblin+A[author]+AND+Melisse">http://www.ncbi.nlm.nih.gov/pubmed/?term=Lamblin+A[author]+AND+Melisse</a>
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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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