

- MELISSE

Head : Lamblin Anne, LEO Pharma France

Last update : 09/10/2014 | Version : 2 | ID : 96

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

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| 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

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| Date of first collection (YYYY or MM/YYYY) | 2008 |
|--|------|

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|---|------|
| Date of last collection (YYYY or MM/YYYY) | 2011 |
|---|------|

Size of the database

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

| | |
|--------------------------------------|-----|
| Details of the number of individuals | 600 |
|--------------------------------------|-----|

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 |
|---------------------------|-----------------------|

Procedures

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| 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 |
|---------------------------------|----|

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

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| 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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