

TROPIQUE - Prescription and Utilisation of Low Molecular Weight Heparin (LMWH) in Usual Medical Practice for the Curative Treatment of Venous Thromboembolism (VTE) in Patients With Cancer.

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General

Identification

Detailed name	Prescription and Utilisation of Low Molecular Weight Heparin (LMWH) in Usual Medical Practice for the Curative Treatment of Venous Thromboembolism (VTE) in Patients With Cancer.
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Sign or acronym	TROPIQUE
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CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL n° 912315 (31/12/12), CCTIRS dossier 12335 (07/06/12)
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General Aspects

Medical area	Cancer research General practice
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Others (details)	Thromboembolism, cancer
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Keywords	Venous thromboembolism, Cancer, LMWH
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Scientific investigator(s) (Contact)

Name of the director	Lamblin
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Unit	LEO Pharma France
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Organization	LEO Pharma
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Collaborations	
Funding	
Funding status	Private
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.	Patients meeting inclusion and exclusion criteria are included consecutively in the study.
Database objective	
Main objective	To document the prescription and the use of LMWH in usual medical practice in France for the treatment of symptomatic VTE in patients with cancer. To assess the conformity of LMWH usage with national recommendations (www.sor-cancer.com et www.thrombose-cancer.com) for VTE treatment in patients with cancer. To evaluate thromboembolism recurrence, bleeding, thrombocytopenia and death as well as document the reasons for discontinuing treatment. To describe clinical factors associated with LMWH treatment duration and those associated with the occurrence of VTE in patients

with cancer. To evaluate anticoagulant treatment perception in cancer patients in order to have a better knowledge of their LMWH treatment satisfaction.

Inclusion criteria

- Men or women aged 18 years or more. Patients who have given oral consent to participate after receiving oral and written information concerning the study. Patients with a solid or liquid tumour confirmed by a histological or cytological examination and receiving anti-cancerous therapy or palliative care. Patients diagnosed with venous thromboembolism (VTE) defined as: - symptomatic proximal or distal deep vein thrombosis (DVP) - confirmed pulmonary embolism (PE) - visceral embolism - thrombosis from a long-term central venous catheter. Patients who have begun curative VTE treatment with LMWH for 7 days or more. Exclusion criteria: Patients treated with LMWH for more than 7 days. Patients presenting contraindications to LMWH use confirmed by respective multidisciplinary meetings.

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

Gender
Male
Woman

Geography area National

Detail of the geography area France

Data collection

Dates

Date of first collection (YYYY or MM/YYYY) 11/2012

Date of last collection (YYYY or MM/YYYY) 01/2014

Size of the database

Size of the database (number of < 500 individuals

individuals)

Details of the number of
individuals

155 (21/03/2013)

Data

Database activity

Current data collection

Type of data collected

Clinical data
Declarative data

Clinical data (detail)

Medical registration

Declarative data (detail)

Face to face interview

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

A satisfaction questionnaire regarding LMWH treatment will be completed by the patient at baseline and at the end of their treatment.

Participant monitoring

Yes

Details on monitoring of
participants

Data on LMWH treatment and different clinical parameters will be gathered at baseline and at 3-month and 6-month follow-up.

Links to administrative sources

No

Promotion and access

Promotion

Link to the document

<http://www.ncbi.nlm.nih.gov/pubmed/25099690>

Link to the document

<http://www.ncbi.nlm.nih.gov/pubmed/?term>

Access

Terms of data access (charter for data provision, format of data, availability delay)

All requests to be sent to LEO Pharma

Access to aggregated data

Access on specific project only

Access to individual data

Access on specific project only