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.
Sign or acronym	TROPIQUE
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)

General Aspects

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

Scientific investigator(s) (Contact)

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Organization	LEO Pharma

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 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