

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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Unit LEO Pharma France

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 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