ARCHIMED HOPITAL - Prevention of venous thromboembolic events with Arixtra 2.5mg for medical ill patients in hospital

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General

Identification

Detailed name	Prevention of venous thromboembolic events with Arixtra 2.5mg for medical ill patients in hospital
Sign or acronym	ARCHIMED HOPITAL
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL : 906317

General Aspects

Medical area	Hematology
Health determinants	Medicine
Keywords	pharmaco-epidemiology, thromboprophylaxis, fondaparinux, arixtra

Scientific investigator(s) (Contact)

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Unit	Laboratoire GSK

Collaborations

Funding

Funding status	Private
Details	GSK laboratory

Governance of the database

Sponsor(s) or organisation(s) responsible	LABORATOIRE GSK
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.	All public and private hospitals that purchase ARIXTRA® 2.5 mg in metropolitan France will be solicited to participate in this study (source: database from the GlaxoSmithKline laboratory). Investigators will be the pharmacists of the hospitals that have accepted to participate in the study. Using the registry kept, the pharmacist will include the first 10 patients responding to the following criteria: ? Patient of at least 18 years of age, ? hospitalized in one of the establishment's care departments (excluding surgery departments), for whom a treatment via ARIXTRA® 2.5 mg is initiated with thromboprophylaxis

Database objective

Main objective	The main objective of this study is to evaluate the average duration of treatment via ARIXTRA® 2.5 mg at the hospital within the framework of the thromboprophylaxis indication
Inclusion criteria	Using the registry kept, the pharmacist will include the first 10 patients responding to the following criteria: ? Patient of at least 18 years of age,

	? hospitalized in one of the establishment's care departments (excluding surgery departments), ? for whom a treatment via ARIXTRA® 2.5 mg is initiated with thromboprophylaxis
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)	2009
Date of last collection (YYYY or MM/YYYY)	2011
Size of the database	
Size of the database (number of individuals)	[500-1000[individuals
Details of the number of individuals	680
Data	
Database activity	Data collection completed
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 care consumption and services
Care consumption (detail)	Hospitalization Medicines consumption
Procedures	
Data collection method	During the first month following the set up of the study in the center, the pharmacist will log in a registry all of the prescription requests for ARIXTRA® 2.5 mg in thromboprophylaxis carried out by his establishment's care departments (excluding surgery departments). The pharmacist will identify the patients that should be included in the study according to the defined eligibility criteria. He will complete a specific inclusion questionnaire for the first 10 patients that meet the eligibility criteria. The pharmacist will complete for each patient included a follow-up questionnaire when released from the hospital.
Participant monitoring	Yes
Details on monitoring of participants	The data that will be collected in the follow-up questionnaire are: ? Premature interruption of the treatment,? total duration of the administration of the treatment, ? prescriptions for prophylactic purposes after the treatment
Links to administrative sources	No
Promotion and access	
Promotion	
Access	
Terms of data access (charter for data provision, format of data, availability delay)	Publications in progress
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only