ARCHIMED VILLE - Prevention of venous thromboembolic events with Arixtra 2.5mg for medical ill patients in general practice

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General

Identification

Detailed name	Prevention of venous thromboembolic events with Arixtra 2.5mg for medical ill patients in general practice
Sign or acronym	ARCHIMED VILLE
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL : 906318

General Aspects

Medical area	General practice
Others (details)	venous thromboembolic events
Keywords	pharmaco-epidemiology, thrombosis, 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 care professionals
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.	Investigators will be selected via random drawing using a complete sampling frame of the general practitioners exercising in metropolitan France. He will complete a specific inclusion questionnaire for the first 3 patients that meet the eligibility criteria.
Database objective	
Main objective	Evaluate the average duration of treatment via ARIXTRA® 2.5 mg with thromboprophylaxis in ambulatory general practice
Inclusion criteria	Patient of at least 18 years of age, -bedridden or with reduced mobility, -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)	2007
Date of last collection (YYYY or MM/YYYY)	2010

Size of the database

Size of the database (number of individuals)	[500-1000[individuals
Details of the number of individuals	834

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 care consumption and services
Care consumption (detail)	Medicines consumption

Procedures

Data collection method	Throughout the entire duration of the study, the doctor will log the prescriptions of ARIXTRA® 2,.5 mg for thromboprophylaxis in a registry. This registry will make it possible to evaluate prescription volume and the representativeness of the patients effectively included in the study. The doctor will

	complete for each patient included a follow-up questionnaire at the end of treatment.
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