ARIANE - Arixtra and platelet monitoring (Study of the actual usage of Arixtra® 2, 5 mg in general practice

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General

Identification

Detailed name	Arixtra and platelet monitoring (Study of the actual usage of Arixtra® 2, 5 mg in general practice
Sign or acronym	ARIANE
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL : 907260

General Aspects

Medical area	General practice
Others (details)	Thrombosis
Keywords	platelet monitoring, pharmaco-epidemiology, observational, thromboprophylaxis

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)	Not-repeated cross-sectional studies (except case control studies)
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 (source: CEGEDIM file. During the entire period of inclusion, the investigating doctor will keep a registry of the eligible patients receiving ARIXTRA® 2.5 mg or an LMWH in thromboprophylaxis. The registry will make it possible to ensure representativeness of patients for whom the doctor will complete the medical questionnaires

Database objective

Main objective	Evaluate and compare in general practice the level of prescription for platelet monitoring of patients receiving Arixtra® 2.5 mg (fondaparinux sodium) or an LMWH (low-molecular-weight heparin) in venous thromboprophylaxis.
Inclusion criteria	? Patient of at least 18 years of age ? Bedridden patient or with reduced mobility Patient for whom a treatment via ARIXTRA® 2.5 mg or an LMWH is initiated within the framework of venous 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)	2008
Date of last collection (YYYY or MM/YYYY)	2009

Size of the database	
Size of the database (number of individuals)	[500-1000[individuals
Details of the number of individuals	910

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	Registry, medical questionnaire
Participant monitoring	No
Links to administrative sources	No
Promotion and access	
Promotion	
Access	
Terms of data access (charter for data provision, format of data, availability delay)	Accepted for publication in "La Presse médicale"
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only