ARISTOTE - Use of Fondaparinux in current clinical practice for thromboprophylaxis following major orthopedic surgery in France

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General

Identification

Detailed name	Use of Fondaparinux in current clinical practice for thromboprophylaxis following major orthopedic surgery in France
Sign or acronym	ARISTOTE
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL n°05-1277

General Aspects

Medical area	Endocrinology and metabolism Traumatology
Others (details)	venous thromboembolic events (VTE), major bleeding
Keywords	orthopedic surgery, pharmaco-epidemiology, thromboprophylaxis, fondaparinux, arixtra

Scientific investigator(s) (Contact)

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Unit	Laboratoire GSK

Collaborations

Funding

Funding status	Private
Details	Laboratoire GSK
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.	The selection of orthopedic surgery departments will be made using the complete list of public or private establishments equipped with a care offering in orthopedic surgery and purchasers of ARIXTRA® 2.5 mg in metropolitan France (ARIXTRA® sales file). In order to ensure the inclusion of a sufficient number of eligible patients by respecting a certain representativeness of the sample, all of the centers will be solicited to participate in the study regardless of their purchase volume of the product. Inclusion: every patient that can potentially be included, i.e. any patient admitted for orthopedic surgery and for whom a prescription of ARIXTRA® 2.5 mg was dispensed in the follow-up from an orthopedic surgical intervention
Database objective	
Main objective	? Describe the actual conditions of use of

	ARIXTRA® 2.5 mg in routine practice after an orthopedic surgical intervention. ? Observe the frequency of occurrence of VTEs during the 6 weeks following the initiation of the treatment via ARIXTRA® 2.5 mg. ? Observe the frequency of occurrence of major bleeding during the 6 weeks following the initiation of the treatment via ARIXTRA® 2.5 mg.
Inclusion criteria	? Patients of at least 18 years of age. ? Patients hospitalized in orthopedic surgery and for whom a treatment via ARIXTRA® 2.5 mg is initiated.
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)	2006
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	608
Data	
Database activity	Data collection completed

Type of data collected	Clinical data Declarative data
Clinical data (detail)	Direct physical measures 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	Collection during the hospitalization of patients in 2 steps: at the inclusion and at the time when released from the department. Collection of data concerning the occurrence of complications (VTE and/or major bleeding) after being released from the department. Data collection will be carried out by the investigating physicians approximately 6 weeks after treatment initiation, at the time of a follow-up consultation in orthopedic surgery or otherwise, a telephone interview. In parallel, during the entire period of inclusion, the investigating physicians will list all patients eligible for the study in a register. Moreover, a collection of data will be carried out specifically with the hospital pharmacy of each participating center
Participant monitoring	Yes
Details on monitoring of participants	6 weeks of follow-up
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