

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

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Last update : 01/01/2019 | Version : 1 | ID : 143

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 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)
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Population covered	Sick population
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Gender	Male Woman
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Geography area	National
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Detail of the geography area	France
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Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	2008
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Date of last collection (YYYY or MM/YYYY)	2009
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Size of the database

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

Database activity	Data collection completed
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Type of data collected	Clinical data Declarative data
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Clinical data (detail)	Medical registration
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Declarative data (detail)	Face to face interview
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Presence of a biobank	No
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Health parameters studied	Health care consumption and services
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Care consumption (detail)	Medicines consumption
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Procedures

Data collection method	Registry, medical questionnaire
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Participant monitoring	No
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Links to administrative sources	No
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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"
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Access to aggregated data	Access on specific project only
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Access to individual data	Access on specific project only
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