SAPHARY - A Safety and Pharmacokinetic study in Real-life practice of Pylera® in France: The SAPHARY study

Head :BLIN Patrick, Bordeaux PharmacoEpi - Université de Bordeaux - Service de Pharmacologie médicale - CIC Bordeaux CIC 1401

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General

Identification

Detailed name	A Safety and Pharmacokinetic study in Real-life practice of Pylera® in France: The SAPHARY study
Sign or acronym	SAPHARY
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CPP: 2012/76, 31/10/2012; EudraCT: 2012-004364-22; CCTIRS: n° 13.427; CNIL: n° 913386

General Aspects

Medical area	Gastroenterology et hepatology
Pathology (details)	Helicobacter Pylori infection
Health determinants	Others (specify)
Others (details)	Medicinal product
Keywords	Bismuth, neurological adverse event, Pylera, Helicobacter Pylori infection, Bordeaux PharmacoEpi, Service de Pharmacologie médicale

Scientific investigator(s) (Contact)

Name of the director	BLIN
Surname	Patrick
Address	Bâtiment du Tondu - Case 41 146 Rue Léo Saignat 33076 BORDEAUX Cedex
Phone	05 57 57 46 75
Email	patrick.blin@u-bordeaux.fr

Unit	Bordeaux PharmacoEpi - Université de Bordeaux - Service de Pharmacologie médicale - CIC Bordeaux CIC 1401
Organization	Université de Bordeaux

Collaborations

Funding

Funding status	Private
Details	Aptalis Pharma

Governance of the database

Sponsor(s) or organisation(s) responsible	Bordeaux PharmacoEpi - Université de Bordeaux - Service de Pharmacologie médicale - CIC Bordeaux CIC 1401
Organisation status	Public
Presence of scientific or steering committees	Yes

Additional contact

Main features

Type of database

Type of database	Study databases
Study databases (details)	Cohort study
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	Yes
Details	Performed at individual level
Additional information regarding sample selection.	The study is a single-arm, open label trial in 200 presumed Helicobacter Pylori-positive subjects and is restricted to centers in France. Following identification of participating general practice and specialist study centers, subjects deemed eligible

	for study will be identified. Subject inclusion in the study will be considered after the decision to treat with Pylera® has been made by investigator. The inclusion visit will be initiated following signature of Informed Consent. The study has an anticipated recruitment period of 24 months. Eligible subjects will stay in study for approximately 6 weeks.
Database objective	
Main objective	The primary objective of the study is to verify the absence of accumulation of bismuth in subjects prescribed Pylera®, a pharmacokinetic approach in a real-life setting.
Inclusion criteria	- Men and women 18 years of age and older who have received a prescription for Pylera® therapy from the Investigator - Mental and legal ability to give written Informed Consent and judged by the Investigator to be capable of following the procedures outlined within the protocol Exclusion criteria : - Women who are pregnant or nursing - Any concern by the Investigator regarding the safe participating of the subject in the study or for any other reason the Investigator considers the subject inappropriate for participating in the study
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
Pathology	B98 - Other specified infectious agents as the cause of diseases classified to other chapters
Gender	Male Woman
Geography area	National
Detail of the geography area	France
Data collection	
Dates	

Date of first collection (YYYY or MM/YYYY)	2014
Date of last collection (YYYY or MM/YYYY)	2016
Size of the database	
Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	200 subjects
Data	
Database activity	Current data collection
Type of data collected	Clinical data Declarative data Biological data
Clinical data (detail)	Direct physical measures
Details of collected clinical data	Medical charts, clinic charts, nurses' notes, medical correspondence regarding the human subject, subject progress notes, pathology reports, laboratory reports, study worksheets, electronic hospital reporting system
Declarative data (detail)	Face to face interview
Details of collected declarative data	Advers event
Biological data (detail)	Whole blood and plasma concentration of bismuth provided prior to start Pyelra® treatment and upon completion of the 10-day treatment with Pylera®
Presence of a biobank	Yes
Contents of biobank	Whole blood Plasma
Details of biobank content	Whole blood and plasma sample
Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services Others
Care consumption (detail)	Medicines consumption

Other (detail)	Whole blood and plasma concentration of bismuth
Procedures	
Data collection method	Paper Case Report Form completed by investigator at each follow-up visit.
Classifications used	MedDRA coding for neurological and non neurological adverse event (SOC and PT); ATC code
Participant monitoring	Yes
Details on monitoring of participants	Eligible subjects will stay in the study for approximately 6 weeks with 2 follow-up visits: the end of treatment visit performed after the 10-day treatment with Pylera®, and the end of study visit performed 28 days post-treatment.
Links to administrative sources	No
Promotion and access	
Promotion	
Access	
Presence of document that lists variables and coding procedures	Yes
Terms of data access (charter for data provision, format of data, availability delay)	A confidentiel study final report has be performed. The ownership of data is defined in a Master Agreement established between the Sponsor, the University of Bordeaux and ADERA (a non-profit making association). The terms of access to the database are to be defined for any third party.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only