SATURNE - Monitoring of chronic Immune Thrombocytopenia (ITP) treated with thrombopoietin receptor (TPO-R) agonists in France

Head :Leclerc-Zwirn Christel, GSK

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General

Identification

Detailed name	Monitoring of chronic Immune Thrombocytopenia (ITP) treated with thrombopoietin receptor (TPO-R) agonists in France
Sign or acronym	SATURNE
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL n°911529

General Aspects

Medical area	Hematology Immunology Rare diseases

Scientific investigator(s) (Contact)

Name of the director	Leclerc-Zwirn
Surname	Christel
Address	100 ROUTE DE VERSAILLES PARIS
Unit	GSK

Collaborations

Funding

Funding status	Private
Details	Laboratoire GSK

Governance of the database

Sponsor(s) or organisation(s)	LABORATOIRE GSK

responsible	
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.	Physician selection: Identification of the physicians via a sampling base consisting of: - The French Hematologists' Directory, - The list of accredited centers, - Internal Medicine departments, A random sample of 1 000 physicians will be extracted from the base. The database will be previously reduced in order to point physicians who manage ITP of adults. 4.4 Patient sample size ITP is a rare disease. In consequence, calculation of the number of subjects needed is based more on the feasibility of recruitment in an acceptable timeframe than on a hard assessment criterion. In view of the incidence and prevalence of ITP and our estimates, recruitment of 200 patients by 60 to 70 participating physicians (active centers) constitutes a feasible objective. However, given that it is highly probable that the patients treated with TPO-R agonists mainly receive care in reference or accredited centers, the participating physicians will be asked to include 3 to 8 patients at TPO-R

Database objective	
Main objective	Describing the profile of patients with chronic ITP treated with TPO-R agonists and the clinical course of their disease over 2 years
Inclusion criteria	Each participating physician is to include in a cross-sectional registry the first patients who are managed for their ITP persistent or chronic. Each physician could fill information about 15 patients maximum. Among the maximum of 15 patients included in the cross-sectional registry, each participating physician is to include in the cohort, in a consecutive manner, the first 3 to 8 patients with chronic ITP at TPO-R agonist treatment initiation in compliance with the inclusion criteria
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)	2012
Date of last collection (YYYY or MM/YYYY)	2014
Size of the database	
Size of the database (number of individuals)	[500-1000[individuals
Details of the number of individuals	500

Data	
Database activity	Data collection completed
Type of data collected	Clinical data Declarative data Biological data Administrative data
Clinical data (detail)	Direct physical measures Medical registration
Declarative data (detail)	Paper self-questionnaire Face to face interview
Biological data (detail)	1. NFS2. Blood film3. TP, TCA, TCK, fibrinogène4. hepatic assessment5. Electrophorèse des protides/protéines6. viral serology: VIH/Hépatitis B and C7. Coombs direct test, ou anti globulin direct test8. Creatinine9. antibody against nuclear endotoxin test10?Myelogram
Administrative data (detail)	socio-demographic data, socio-professional group, (CSP), ethnic group
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services Quality of life/health perception
Care consumption (detail)	Hospitalization Medical/paramedical consultation Medicines consumption
Procedures	
Data collection method	Throughout the study, data acquisition will be implemented via an electronic CRF (e-CRF). In order to analyze the time course of the quality of life and satisfaction of patients with chronic ITP treated with a TPO-R agonist, a quality of life and satisfaction questionnaire will be supplied to the patients taking part in the study
Participant monitoring	Yes
Details on monitoring of participants	In order to achieve the primary objective, the physicians will be asked to fill out the e-CRF at time points: M0, M3, M6, M12, M18 and M24

Links to administrative sources	No
Promotion and access	
Promotion	
Access	
Terms of data access (charter for data provision, format of data, availability delay)	Publication
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only