Les STIMS - Patients who did not relapse after stopping tyrosine kinase inhibitor treatment for chronic myeloid leukaemia

Head :Mahon François-Xavier, Hématopoïèse Leucémique et Cible thérapeutiques
Bouvier Séverine

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General

Identification

Detailed name	Patients who did not relapse after stopping tyrosine kinase inhibitor treatment for chronic myeloid leukaemia
Sign or acronym	Les STIMS
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL n°1245229

General Aspects

Medical area	Immunology
Keywords	Tyrosine kinase inhibitors, stopping treatment, complete molecular remission, relapse.

Scientific investigator(s) (Contact)

Name of the director	Mahon
Surname	François-Xavier
Address	Université Bordeaux Ségalen, 146 rue Léo Saignat, 33076 BORDEAUX
Phone	+ 33 (0)5 57 57 15 24
Email	Francois-Xavier.Mahon@u-bordeaux2.fr
Unit	Hématopoïèse Leucémique et Cible thérapeutiques
Organization	Université Bordeaux
Name of the director	Bouvier

Surname	Séverine
Collaborations	
Funding	
Funding status	Mixed
Details	PHRC 2006
Governance of the database	
Sponsor(s) or organisation(s) responsible	Université Bordeaux Ségalen
Organisation status	Public
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.	Subjects meeting inclusion and exclusion criteria must sign a consent
Database objective	
Main objective	To monitor patients who discontinued tyrosine kinase inhibitors for at least two years in order to determine their molecular status and collate potential late molecular relapses.
Inclusion criteria	Men or women aged 18 years and older Chronic myeloid leukaemia in chronic or accelerated phase under treatment with Imatinib for at least 3 years Complete molecular remission under treatment with Imatinib for at least 2 years For the women old

	enough to procreate, a method of effective contraception Subjects covered by or affiliated with a social security scheme Negative HIV serology and absence of chronic hepatitis B or C Free and informed consent in writing Molecular monitoring as recommended by European "LeukemiaNet"
Population type	
Age	Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years) Elderly (65 to 79 years)
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)	2010
Size of the database	
Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	100
Data	
Database activity	Current data collection
Type of data collected	Clinical data Biological data
Clinical data (detail)	Medical registration
Biological data (detail)	BCR-ABL transcript level
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	After the accuracy of the data is verified, they are collected by mail or directly on site by the person in charge of verification every 3-6 months. The same person enters the data in an Access database, which is then transferred to a biostatistician. This is done centrally.
Participant monitoring	Yes
Details on monitoring of participants	The BCR-ABL transcript level is measured by quantitative RT-PCR in molecular biology laboratories every 3 months following a blood sample from the patient.
Links to administrative sources	No
Promotion and access	
Promotion	
Link to the document	http://tinyurl.com/Pubmed-STIMS
Description	List of publications in Pubmed
Access	
Terms of data access (charter for data provision, format of data, availability delay)	Publications Data are accesible by other researchers by request if required (via secure Excel files graphics, etc.)
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only