

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

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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)

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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 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)
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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)	2010
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Size of the database

Size of the database (number of individuals)	< 500 individuals
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Details of the number of individuals	100
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Data

Database activity	Current data collection
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Type of data collected	Clinical data Biological data
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Clinical data (detail)	Medical registration
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Biological data (detail)	BCR-ABL transcript level
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Presence of a biobank	No
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Health parameters studied	Health event/morbidity
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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