

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 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 accessible 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