PERLE - Prospective pharmaco-epidemiological study aiming to describe the management of relapsed or refractory chronic lymphocytic leukemia (CLL) patients retreated with MabThera®

Head :Roche Medical data center

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General

Identification

Detailed name	Prospective pharmaco-epidemiological study aiming to describe the management of relapsed or refractory chronic lymphocytic leukemia (CLL) patients retreated with MabThera®
Sign or acronym	PERLE
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	ML25664

General Aspects

Medical area	Hematology
Study in connection with Covid-19	No
Pathology (details)	Chronic Lymphocytic Leukemia
Health determinants	Medicine
Keywords	rituximab

Scientific investigator(s) (Contact)

Name of the director	Roche Medical data center
Address	4 cours de l'Ile Seguin - 92100 Boulogne-Billancourt
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Organization	Roche SAS

Collaborations

Participation in projects,	No

networks and consortia

Funding	
Funding status	Private

Governance of the database	
Sponsor(s) or organisation(s) responsible	Roche SAS
Organisation status	Private
Presence of scientific or steering committees	Yes

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 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	No

Database objective	
Main objective	Primary Objective: To describe the chemotherapy regimens combined with MabThera® in relapsed or refractory CLL patients having previously received a first or second-line treatment containing MabThera® Secondary Objectives: - Describe efficacy of treatment: overall response (OR), complete response (CR), partial response (PR), progression-free survival (PFS), time to next treatment (TTNT), overall survival (OS) in the total cohort and in the following subgroups: refractory (Yes/No), age (< or >= 70 years), 17p deletion (Yes/No), 11q deletion (Yes/No). - Describe the choice of chemotherapy regimen in patient subgroups defined as: refractory (Yes/No),

	age (< or >= 70 years), 17p deletion (Yes/No), 11q deletion (Yes/No) - Describe MabThera® treatment regimens (dose, number of cycles), - Describe safety of treatment: all adverse events occurring during the study, - Describe hospitalizations related to an adverse event throughout the study period. Exploratory Objectives: -Analysis of maximal response duration at last line before inclusion will be performed quantitatively and by classes, overall and by age, in all patients and according to number of previous lines of treatment. - Primary criterion will be also described according to the following subgroups: - last previous treatment before current relapse included the same/not the same chemotherapy treatment as first induction treatment - report of Normalized creatinine clearance result < 60 (ml/min/1.73 m^2) at baseline (yes/no) (renal insufficiency). - In patients with HBs antigen positive or anti-HBc antibody positive, analysis of HBV prophylaxis and HBV treatment will be performed by visit - Multinomial regression on choice of chemotherapy given at first cycle - Logistic model on response
Inclusion criteria	Inclusion criteria: - Adult patient (age >= 18 years) - Presenting with chronic lymphocytic leukemia confirmed by immunophenotyping of circulating lymphocytes (Matutes score >= 4) - In relapse or refractory after a first or second line of treatment - Receiving at least one line of treatment containing MabThera® - MabThera® treatment planned for current relapse - Having received oral and written information about the study and having raised no objections to computer processing of his/her personal data. Exclusion criteria: - Patient with Richter syndrome - Patient with life expectancy < 6 months - Patient who received 3 or more previous treatment lines* - Patient previously enrolled in this 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	C81-C96 - Malignant neoplasms, stated or presumed to be primary, of lymphoid, haematopoietic and related tissue
Gender	Male Woman
Geography area	National
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	2011
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	327
Data	
Database activity	Data collection completed
Type of data collected	Clinical data
Clinical data (detail)	Medical registration
Details of collected clinical data	Type of data collected : previous medical history and concomitant disorders, cycles of therapy administered, laboratory test data, efficacy, evaluation of patient, adverse events, early permanent discontinuation, history of CLL, verification of screening criteria before inclusion, treatment programme initially planned for treatment of this relapse (or of this refractory condition) of CLL, current relapse (or refractory condition) of CLL, previous treatments of CLL, demographic data, prophylaxis or anti-infective treatment, hematopoietic stem cell transplantations, Richter's syndrome.

Presence of a biobank	No
Procedures	
Data collection method	eCRF
Classifications used	CDISC like
Quality procedure(s) used	GCP/GVP
Participant monitoring	Yes
Monitoring procedures	Monitoring by contact with the referring doctor
Followed pathology	C81-C96 - Malignant neoplasms, stated or presumed to be primary, of lymphoid, haematopoietic and related tissue
Links to administrative sources	No
Promotion and access	
Promotion	
Access	
Dedicated website	https://www.roche.fr/fr/innovation-recherche-medicale/data-sharing-portail-d-information-partage-des-donnees.html
Presence of document that lists variables and coding procedures	Yes
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only