LEA - Multicentric prospective cohort of children and adolescents malignant hemopathies

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Général

Identification

Nom détaillé	Multicentric prospective cohort of children and adolescents malignant hemopathies
Sigle ou acronyme	LEA
Numéro d'enregistrement (ID-RCB ou EUDRACT, CNIL, CPP, etc.)	CNIL n°05-1094, ANSM B120924-30, CPP 12.074 (n° ID-RCB 2012-A00984-39)

Thématiques générales

Domaine médical	Cancer research Hematology
Déterminants de santé	Iatrogenic
Mots-clés	Malignant hemopathies, Leukemia, Lymphoma, Sequelae of leukemia or its treatment, long term adverse side effects, children, adolescents

Responsable(s) scientifique(s)

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Collaborations

Financements

Financements	Mixed
Précisions	PHRC, INCA, ARH, Conseil régional PACA, ANR Investissement d'avenir dans le cadre du projet HOPE-EPI

Gouvernance de la base de données

Organisation(s) responsable(s) ou promoteur	Assistance Assistance Publique des Hopitaux de Marseille (APHM)

Statut de l'organisation	Secteur Public

Contact(s) supplémentaire(s)

Caractéristiques

Type de base de données

Type de base de données	Study databases
Base de données issues d'enquêtes, précisions	Cohort study
Origine du recrutement des participants	A selection of health institutions and services
Le recrutement dans la base de données s'effectue dans le cadre d'une étude interventionnelle	No
Informations complémentaires concernant la constitution de l'échantillon	The study began in 2004 by an exhaustive recruitment of incident cases (diagnosed since 01/01/2006) and of prevalent cases (diagnosed between 01/01/1980 and 31/12/2005) in the Pediatric and pediatric hematology departments of the CHU of Marseille and Nice (PACA region), and the CHU of Nancy (Lorraine region). In a second time, the teams of Clermont-Ferrand (Auvergne) and Grenoble (Rhône-Alpes) joined the project respectively in 2008 and 2009. Then, teams of Lyon (Rhône-Alpes), Paris (Robert Debré, St. Louis et Trousseau) and St. Etienne began to include respectively in 2010 and 2011. Finally, teams of Montpellier, Rennes, Bordeaux and Strasbourg joined the LEA program in 2012.Malignant hemopathies are identified in pediatric and pediatric hematology departments.In all regions corresponding to the LEA study investigation centers, all children and adolescents malignant hemopathy cases are treated into one of the pediatric hematology departments participating to the LEA program, in the period following the diagnosis, in the perspective of medical care.

Objectif de la base de données

Objectif principal	General objective of the project : Describe the evolution at short and medium term of a cohort of patient treated for malignant hemopathy during their childhood, concerning: . quality of life in patient and its relatives . socio-economic insertion

	. health condition . relation to the health care system Study the determinants (medical, socio-economic, behavioral or environmental) of the evolution (health condition and quality of life) at medium and long term of a cohort of patients treated for malignant hemopathy during their childhood. Study predictive factors of the occurrence of long term sequelae of height and weight growth, puberty, fertility, thyroid function, visual function, cardiac function, viral contamination, pulmonary function, bone metabolism, iron metabolism, metabolic syndrome, other sequelae. Explore mortality/survival of the patients of this cohort after malignant hemopathy treatment in childhood. Compare the quality of life in patients treated for malignant hemopathy to the one of subjects of same gender and age, control subjects in good health or suffering of chronic diseases. Project perspectives: Concerning literature, knowledge of the determinants of health condition and quality of life in patients after a malignant hemopathy treatment during childhood is today too fragmented to propose care strategies to improve the future of these children. Taking into account the constitution limits of the Childhood Cancer Survivor Study, the cohort LEA showed its feasibility on the period 2004-2013. Nevertheless, today it's necessary to enlarge the representative base of this cohort, joining to the project the large care centers for children malignant hemopathies in France, and creating a more multi-disciplinary research consortium (HOPE-EPI). Funding requested in the context of ANR (Great loan) aim to carry on the work realized and to improve the program on the following main points: rise of the number of patients included, taking into account of largest panel of determinants, association with new clinical research teams. A partnership with the national register of children malignant hemopathies (directed by J.Clavel) will be established, allowing to optimize completeness of the active thread. Moreover, actual large multi-central French protocols for children lymphoblastic and myeloblastic acute leukemia treatment (EORTC, FRALLE, ELAM) are represented in the project by the inclusion of new centers.
Critères d'inclusion	Patients with lymphoma, acute lymphoblastic and

	myeloblastic leukemia, aged less than 18 at the moment of the diagnosis, and diagnosed after January 1980. Patients are in a condition of hematological remission, and the treatment of the acute leukemia has begun in one of the investigation centers. Other criteria: resident in France, agree to participate, or parents agree for their minor children participation.
Type de population	
Age	Newborns (birth to 28 days) Infant (28 days to 2 years) Early childhood (2 to 5 years) Childhood (6 to 13 years) Adolescence (13 to 18 years) Adulthood (19 to 24 years) Adulthood (25 to 44 years)
Population concernée	Sick population
Sexe	Male Woman
Champ géographique	National
Détail du champ géographique	At the beginning, the project implied pediatric and pediatric hematology departments of the CHU Marseille (PACA-West and Corse) and CHU Nancy (Lorraine). As a second step, the teams of CHU Nice (PACA-East), Clermont Ferrand (Auvergne) and Grenoble (Rhône-Alpes) joined the project, and have been included respectively in 2007, 2008, and 2009. In 2010, the Lyon Institute of Hematology and Pediatric Oncology joined the project, followed in 2011 by 3 Parisian centers (St. Louis, Robert Debré, Trousseau) and St. Etienne (Rhône-Alpes). Finally, the CHU of Rennes (Bretagne) and Montpellier (Languedoc-Roussillon) began to include in 2012. Half -2012, the CHU of Bordeaux and Strasbourg committed to the preparatory phase for inclusion.
Collecte	
Dates	
Année du premier recueil	04/2004
Taille de la base de données	
Taille de la base de données (en	[1000-10 000[individuals

nombre d'individus)	
Détail du nombre d'individus	2385 patients (2003+2007+2008+2009+2010+2011+2012+2013)

Données

Activité de la base	Current data collection
Type de données recueillies	Clinical data Declarative data Paraclinical data Biological data
Données cliniques, précisions	Direct physical measures
Données déclaratives, précisions	Paper self-questionnaire
Données paracliniques, précisions	Concerning transplanted patients follow-up, a thyroid echography is realized, as well as Pulmonary Function Test. All patients get a cardiac echography ; patients over 10 years old receive a Bone Mineral Density test too.
Données biologiques, précisions	Concerning medical follow-up of patients, blood samples are taken and data concerning biological usual parameters are collected.
Existence d'une biothèque	No
Paramètres de santé étudiés	Health event/morbidity Quality of life/health perception

Modalités

Mode de recueil des données	For the incident cases, data collection is organized in a prospective way at fixed term from the initial date of the diagnosis. For the prevalent cases, data collected are similar to the ones collected for the incident cases. The only difference is the collection method, which is retrospective for events concerning the period before the centers participation to LEA program (information concerning diagnosis, treatments set up, health occurence including death, relapses, organic sequelae of treatments), while it's in a perspective way for incident cases.Data collected concern explanatory variables characterizing patients' health condition and quality of life, and on the other hand variables describing factors considered as potentials determinants. Between these potential

	determinants, will be considered factors defined at the individual level (clinic, demographic?) but also population factors (environment?).Data collected:- socio-demographic and socio-economic concerning the patient and its family;- clinical and therapeutic data concerning the disease (LA): nature, age at diagnosis, severity, treatments, recovery distance?);- concerning clinical examination and eventual organic sequelae: height and weight growth puberty, fertility, thyroid function, visual function, cardiac function, viral contamination, pulmonary function, bone metabolism, iron metabolism, metabolic syndrome, other sequelae (diabetes, osteonecrosis, chronic renal insufficiency, alopecia, central nervous system?);- psychological, behavioral and cognitive; - concerning quality of life in patients and their relatives;- concerning patient relation with health care system (care access and satisfaction);
Suivi des participants	Yes
Détail du suivi	Follow-up duration undefined
Appariement avec des sources administratives	Yes
Sources administratives appariées, précisions	Hospital diagnosis-related group database (PMSI), to check the exhaustiveness of population included in the study.

Valorisation et accès

Valorisation et accès

Lien vers le document	http://tinyurl.com/Publi-HAL-LEA
Description	List of publications in HAL
Lien vers le document	http://tinyurl.com/Pubmed-LEA
Description	List of publications in Pubmed

Accès

Charte d'accès aux données (convention de mise à disposition, format de données et délais de mise à disposition)	Oral communications concerning the study are regularly presented during annual cohort days (gathering all the investigation centers), during ? cancéropole?days, during workshops at SFCE.
Accès aux données agrégées	Access on specific project only
Accès aux données individuelles	Access on specific project only