LEA - Multicentric prospective cohort of children and adolescents malignant hemopathies

Head :Auquier Pascal, EA 3279 - Santé Publique et Maladies Chroniques : Qualité de vie, Concepts, Usages et limites, Déterminants.
Michel Gérard, EA 3279 - Santé Publique et Maladies Chroniques : Qualité de vie, Concepts, Usages et limites, Déterminants.
Simeoni Marie-Claude, EA 3279 - Santé Publique et Maladies Chroniques : Qualité de vie, Concepts, Usages et limites, Déterminants.

Last update : 02/11/2014 | Version : 2 | ID : 3269

General

Identification

Detailed name	Multicentric prospective cohort of children and adolescents malignant hemopathies
Sign or acronym	LEA
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL n°05-1094, ANSM B120924-30, CPP 12.074 (n° ID-RCB 2012-A00984-39)

General Aspects

Medical area	Cancer research Hematology
Health determinants	Iatrogenic
Keywords	Malignant hemopathies, Leukemia, Lymphoma, Sequelae of leukemia or its treatment, long term adverse side effects, children, adolescents

Scientific investigator(s) (Contact)

Name of the director	Auquier
Surname	Pascal
Address	UFR Médecine - Site Timone - EA 3279 / 27 Bd Jean Moulin / 13385 Marseille Cedex 05
Phone	+ 33 (4) 91 38 47 44
Email	pascal.auquier@univ-amu.fr

Unit	EA 3279 - Santé Publique et Maladies Chroniques : Qualité de vie, Concepts, Usages et limites, Déterminants.
Organization	Assistance Publique-Hôpitaux de Marseille (APHM), Aix-Marseille
Name of the director	Michel
Surname	Gérard
Address	Hôpital de la Timone - 264 rue St Pierre - 13005 Marseille
Phone	+ 33 (4) 91 38 67 76
Email	gmichel@ap-hm.fr
Unit	EA 3279 - Santé Publique et Maladies Chroniques : Qualité de vie, Concepts, Usages et limites, Déterminants.
Organization	Assistance Publique-Hôpitaux de Marseille (APHM), Aix-Marseille
Name of the director	Simeoni
Surname	Marie-Claude
Phone	+ 33 (4) 91 38 47 44
Email	marie-claude.simeoni@univ-amu.fr
Unit	EA 3279 - Santé Publique et Maladies Chroniques : Qualité de vie, Concepts, Usages et limites, Déterminants.
Organization	Assistance Publique-Hôpitaux de Marseille (APHM), Aix-Marseille

Collaborations

Funding

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

Governance of the database

Sponsor(s) or organisation(s) responsible	Assistance Assistance Publique des Hopitaux de Marseille (APHM)
Organisation status	Public

Additional contact

Main features

Type of database

Type of database	Study databases
Study databases (details)	Cohort study
Database recruitment is carried out by an intermediary	A selection of health institutions and services
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	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.

Database objective

Main objective	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.

Inclusion criteria	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.

Population type

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 covered	Sick population
Gender	Male Woman
Geography area	National
Detail of the geography area	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.

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	04/2004

Size of the database

Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	2385 patients (2003+2007+2008+2009+2010+2011+2012+2013)

Data

Database activity	Current data collection
Type of data collected	Clinical data Declarative data Paraclinical data Biological data
Clinical data (detail)	Direct physical measures
Declarative data (detail)	Paper self-questionnaire
Paraclinical data (detail)	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.
Biological data (detail)	Concerning medical follow-up of patients, blood samples are taken and data concerning biological usual parameters are collected.
Presence of a biobank	No
Health parameters studied	Health event/morbidity Quality of life/health perception

Procedures

Data collection method	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);
Participant monitoring	Yes
Details on monitoring of participants	Follow-up duration undefined
Links to administrative sources	Yes
Linked administrative sources (detail)	Hospital diagnosis-related group database (PMSI), to check the exhaustiveness of population included in the study.

Promotion and access

Promotion

Link to the document	http://tinyurl.com/Publi-HAL-LEA
Description	List of publications in HAL
Link to the document	http://tinyurl.com/Pubmed-LEA
Description	List of publications in Pubmed

Access

Terms of data access (charter for data provision, format of data, availability delay)	Oral communications concerning the study are regularly presented during annual cohort days (gathering all the investigation centers), during ? cancéropole?days, during workshops at SFCE.
Access to aggregated data	Access on specific project only

Access to individual data	Access on specific project only