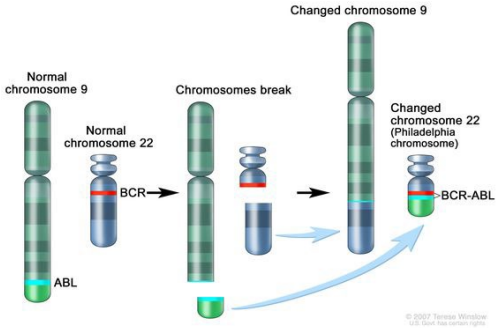
International Registry of Chronic Myeloid Leukemia in Children and Adolescents

I CML Ped Study

International Study of Chronic Myeloid Leukemia (CML) treatment and outcomes of children and adolescents – **I-CML-Ped Study**

GENERAL INFORMATION

Chronic myeloid leukemia (CML) is a malignant disease of the blood and bone marrow. It is characterized by excessive and persistent production of white blood cells (or leukocytes) in the bone marrow. The disease is linked to the appearance of an abnormality associated with the fusion of two chromosomes in bone marrow stem cells, resulting in the appearance of a small abnormal chromosome, the Philadelphia chromosome. The causes of its genesis are as yet unknown.



For more information on CML: https://lmc-cml.org/

CML is a rare disease in children and adolescents, accounting for between 2% and 3% of childhood leukemias. The characteristics of this disease have not been fully described, and treatment modalities are not well defined in this age group. Thanks to advances in research, this disease has benefited from new treatments for several years now.

In 2011, we set up the International Childhood and Adolescent CML Registry (I-CML-Ped Study) at the Poitiers University Hospital, to advance knowledge of this disease and improve treatment. We record data on all CML patients under 18 years of age (regardless of disease stage, type of treatment, etc.). This study gathers retrospective data (patients with a diagnosis from 2000 onwards) and prospective data contained in patients' clinical records and/or in existing databases.

July 2024

MAIN OBJECTIVES

The main objectives of this study are as follows :

1-Describe the characteristics of CML in a cohort of patients under the age of 18

2-List therapeutic strategies

3-Identifying prognostic factors

4-Determine a prognostic score to optimize individual treatment choices

5-Determining the side effects and long-term effects of treatments

POPULATION

All patients under 18 years of age with newly diagnosed CML are eligible. Patients are eligible regardless of disease stage, type of treatment, and whether or not they are in a clinical trial.

METHODS

The registry received CNIL (Commission Nationale de l'Informatique et des Libertés) authorization on 3rd december 2010, and a favorable opinion from CCTIRS (Comité Consultatif sur le Traitement de l'Information en matière de Recherche dans le domaine de la Santé) on 29th october 2009. It is registered on ClinicalTrials.gov under identifier number : NCT01281735.

The study is strictly observational. It gathers retrospective and prospective data from patients' clinical records and/or existing databases.

REGISTRATION PROCESS

Registration procedure and data collection :

1-Consent gathering
- Consent for parents,
- Consent for minors
- Consent for adult patients diagnosed as minors.

2-Send the registration form to the CRA in charge of the study, Micheline KABORE, by fax (+33549444691) or e-mail (barkwende-mecheline.kabore@chu-poitiers.fr)

PARTICIPATING CENTERS / COUNTRIES

In France, patients can be registered at the 30 SFCE centers (Société Française de lutte contre les Cancers de l'Enfant et de l'Adolescent).

Internationally, 17 countries are currently participating in the data collection :

Austria, Belarus, Belgium, Brazil, Croatia, Czech Republic, Denmark, France, Germany, Greece, Hong Kong, Lebanon, Netherlands, Poland, Slovakia, Spain, Turkey.

STUDIES IN PROGRESS IN 2024

- *Piramid* : CML Pediatric ITK Response According to Molecular Identification at Diagnosis

Search for a molecular signature at diagnosis of children with Chronic Myeloid Leukemia to predict response to tyrosine kinase inhibitors. Collaboration with CHU Bordeaux.

- Characteristics and outcome of children receiving allogeneic transplantation for CML
- Weight gain in children treated with Imatinib for CML
- Description of mutations listed in the international register

LINKS

Patient association: LMC France *(https://www.lmc-france.fr)*

International BFM Study Group:
https://bfminternational.wordpress.com/structure/committees/chronic-myeloid-leukemia-committee-cml/

RIGHTS

Patients or parents whose children are involved in this study may object to the use of their data at any time.
If they have any questions or wish to exercise their rights (or those of their beneficiaries), they can contact the Data Protection Officer (DPO) at Poitiers University Hospital :
> by e-mail to the following address: dpo@chu-poitiers.fr or
> by post : CHU de Poitiers - Direction Générale, Délégué à la Protection des Données - 2 Rue de la Milétrie - 86021 POITIERS CEDEX (France)

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July 2024