National Longitudinal Cohort of Hematological Diseases - Bone Marrow Transplantation (NICHE- BMT)

Applicant: Institute of Hematology & Blood Diseases Hospital

Version: 1.0

NCT Number: NCT04645199

Date: 15-Dec-2020

National Longitudinal Cohort of Hematological Diseases- Bone Marrow Transplantation (NICHE-BMT)

Background

Hematological diseases are disorders of the blood and hematopoietic organs. The current hematological cohorts are mostly based on single-center or multi-center cases, or cohorts with limited sample size in China. There is a lack of comprehensive and large-scale prospective cohort studies in hematology.

Objectives

The objectives of this study are to investigate the characteristics of patients received bone marrow transplantations and to analyze the treatment methods, prognosis and medical expenses of these patients in China.

Subjects

Patients who were received bone marrow transplantations in the investigating hospitals from February 7, 2021.

Method

The NICHE-BMT will collect basic information, diagnostic and treatment information, as well as medical expense information of patients from medical records. The study will use questionnaire to measure the exposure of patients, and prospectively follow-up to collect the prognosis information.

Statistical Analysis Plan

Statistical analyses will be performed using SAS 9.4 (SAS Institute Inc., Cary, NC, USA) software. For the categorical variables, the results will be presented as counts and percentages. The differences between groups were compared with Chi-square test or Fisher's exact test. For continuous variables, mean ± SD or median (P25, P75) will be presented according to the distributions. The differences between groups were compared with ANOVA or Wilcoxon rank-sum test. For time-to-event variables, the incidences of events were described using the Kaplan-Meier method and compared between groups using the log-rank test. Cox proportional hazard regression modes were used for multivariate analyses. A P-value of less than 0.05 was considered to indicate statistical significance.

National Longitudinal Cohort of Hematological Diseases

- Pediatric hematological diseases

(NICHE- Pediatrics)

Applicant: Institute of Hematology & Blood Diseases Hospital

Version: 1.0

NCT Number: NCT04645199

Date: 9-Dec-2020

National Longitudinal Cohort of Hematological Diseases- Pediatric Hematological Diseases (NICHE- Pediatrics)

Background

Hematological diseases are disorders of the blood and hematopoietic organs. The current hematological cohorts are mostly based on single-center or multi-center cases, or cohorts with limited sample size in China. There is a lack of comprehensive and large-scale prospective cohort studies in hematology.

Objectives

The objectives of this study are to investigate the incidence and risk factors of AML, ALL, AA, IBMFS, MPN, et al. and to analyze the treatment methods, prognosis and medical expenses of these pediatric patients in China.

Subjects

Pediatric patients who were diagnosed with AML, ALL, AA, IBMFS and MPN, et al. in the investigating hospitals from February 3, 2021.

Method

The NICHE-Pediatrics will collect basic information, diagnostic and treatment information, as well as medical expense information of patients from medical records. The study will use questionnaire to measure the exposure of patients, and prospectively follow-up to collect the prognosis information.

Statistical Analysis Plan

Statistical analyses will be performed using SAS 9.4 (SAS Institute Inc., Cary, NC, USA) software. For the categorical variables, the results will be presented as counts and percentages. The differences between groups were compared with Chi-square test or Fisher's exact test. For continuous variables, mean ± SD or median (P25, P75) will be presented according to the distributions. The differences between groups were compared with ANOVA or Wilcoxon rank-sum test. For time-to-event variables, the incidences of events were described using the Kaplan-Meier method and compared between groups using the log-rank test. Cox proportional hazard regression modes were used for multivariate analyses. A P-value of less than 0.05 was considered to indicate statistical significance.