ANHL1131: Intergroup Trial for Children or Adolescents with B-Cell Non-Hodgkin Lymphoma (NHL) or Mature B-Cell Leukemia B-AL: Evaluation of Rituximab Efficacy and Safety in High Risk Patients.

PURPOSE: This randomized phase II/III trial studies how well giving combination chemotherapy with or without rituximab works in treating younger patients with stage III or stage IV non-Hodgkin lymphoma or B-cell acute leukemia. Drugs used in chemotherapy work in different ways to stop the growth of cancer cells, either by killing the cells or by stopping them from dividing. Monoclonal antibody, such as rituximab, can block cancer cells growth in different ways. Some block the ability of cancer cells to grow and spread. Others find cancer cells and help kill them or carry cancer-killing substances to them. It is not yet known whether giving combination chemotherapy together with rituximab is more effective in treating patients with non-Hodgkin lymphoma or B-cell acute leukemia.

Study Type: Interventional
Masking: Open Label
Primary Purpose: Treatment

AGES ELIGIBLE FOR STUDY: up to 18 Years

Criteria

Inclusion Criteria:

- Histologically or cytologically proven B-cell malignancies; Burkitt leukemia or B-cell acute leukemia (B-AL) (Burkitt leukemia = L3-AL), or diffuse large B-cell non-Hodgkin lymphoma (NHL), or aggressive mature B-cell NHL not otherwise specified or specifiable (phase III)
    - Stage III with elevated LDH level (B-high) [LDH > twice the institutional upper limit of the adult normal values (> Nx2)], any stage IV, or B-AL (phase III)
- Histologically or cytologically proven primary mediastinal large B-cell lymphoma (PMLBL) (phase II)
    - No central nervous system (CNS) involvement
- No follicular lymphoma, mucosa-associated lymphoid tissue (MALT) lymphoma, or nodular marginal zone lymphoma
- Tumor cell negative for CD20 (absence of result due to technical problems in the presence of other characteristics suggestive of BL/DLBCL, including genetic and phenotypic features, is not an exclusion criteria)
- Males and females of reproductive potential must agree to use an effective contraceptive method during the treatment, and after the end of treatment: 12 months for women and 5 months for men
- Able to comply with scheduled follow-up and with management of toxicity
- Signed informed consent from patients and/or their parents or legal guardians

- No patients with congenital immunodeficiency, chromosomal breakage syndrome, prior organ transplantation, previous malignancy of any type, or known positive human immunodeficiency virus (HIV) serology
- Not pregnant or nursing
- No severe active viral infection, especially hepatitis B virus (HBV)
    - Severe infection (such as sepsis, pneumonia, etc.) should be clinically controlled at the time of randomization
- No HBV carrier status or positive serology; a patient is considered as HBV carrier or to have (had) HBV infection by any of the following criteria:
    - Unimmunized and hepatitis B surface antigen (HBsAg) and/or anti-HBs antibody and/or anti-hepatitis B core (HBc)-antibody positive
    - Immunized and HBsAg and/or anti-HBc antibody positive
    - For the Phase III trial, a patient without a known history of HBV could be randomized in the study if the serology results are not available at the time of the randomization; however, if the serology results are positive or not available at day 6 (the first day to receive rituximab, if so randomized), the patient must be withdrawn from the study whatever the allocated treatment arm; for the phase II trial, the hepatitis B serology results must be available before registration
- No patients who, for any reason, are not able to comply with the national legislation
- No past or current anti-cancer treatment except corticosteroids for less than one week
- No participation in another investigational drug clinical trial
- No prior exposure to rituximab

For more information contact:
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