Caloric Restriction and Activity to Reduce Chemoresistance in B-ALL

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 7 years to 25 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

- Patients must be ≥ 7.0 and <26.0 years of age.
- Patients must have a diagnosis of de novo B-ALL
- Patients must have a M3 marrow (>25% blasts by morphology) or at least 1,000/µL circulating leukemia cells in PB confirmed by Flow Cytometry (or other convincing evidence of a B-ALL diagnosis not meeting above criteria following central review by the Study Hematopathologist and Study Chair or Vice-Chair).
- The treatment regimen must be the first treatment attempt for B-ALL-
- Must be a multi-agent induction regimen inclusive of vincristine, glucocorticoid, pegaspargase/calaspargase, and daunorubicin or doxorubicin and with a planned duration <35 days.
- Organ function must meet that required for initiation of chemotherapy
- Patients at diagnosis must meet Karnofsky > 50% for patients > 16 years of age and Lansky > 50% for patients ≤ 16 years of age (or be expected to recover prior to Day 8) .
- If the patient is a female of childbearing potential, a negative urine or serum pregnancy test is required within two weeks prior to enrollment.

Exclusion Criteria:

- Patient will be excluded if they are underweight at time of enrollment (BMI% <5th percentile for age for patients age 10-19 years, BMI <18.5 in patients 20-29 years).
- Patients with Down syndrome or a DNA fragility syndrome (such as Fanconi anemia, Bloom syndrome) will be excluded.
- Patient receiving a SJCRH-style "Total Therapy" regimen will be excluded.
- Patients receiving anti-CD20 monoclonal antibody therapy during induction therapy.
- Patients will be excluded if they received treatment for a previous malignancy.
- Patient will be excluded if they are pregnant.
- Patient will be excluded if they have a pre-diagnosis requirement for enteral or parenteral supplementation .
- Patient will be excluded due to inability to perform the intervention (e.g., specific nutritional needs, severe developmental delay, paraplegia)
- Patients will be excluded if they have significant concurrent disease, illness, psychiatric disorder or social issue that would compromise patient safety or compliance with the protocol treatment or procedures, interfere with consent, study participation, follow up, or interpretation of study results

Conditions & Interventions

Interventions:
BEHAVIORAL: IDEAL2 Intervention
Conditions:
B-cell Acute Lymphoblastic Leukemia, Obesity
Keywords:
obesity, leukemia, B-cell leukemia, Pediatric obesity, Pediatric ALL

More Information

Description:
This study is for older children, adolescents, and young adults with B-cell Acute Lymphoblastic Leukemia (B-ALL). Higher amounts of body fat is associated with resistance to chemotherapy in patients with B-ALL. Chemotherapy during the first month causes large gains in body fat in most people, even those who start chemotherapy at a healthy weight. This study is being done to find out if caloric restriction achieved by a personalized nutritional menu and exercise plan during routine chemotherapy can make the patient's ALL more sensitive to chemotherapy and also reduce the amount of body fat gained during treatment. The goals of this study are to help make chemotherapy more effective in treating the patient's leukemia as demonstrated by fewer patients with leukemia minimal residual disease (MRD) while also trying to reduce the amount of body fat that chemotherapy causes the patient to gain in the first month.

Contact(s): cancer@cchmc.org
Principal Investigator:
Principal Investigator ID:
Phase: PHASE2
IRB Number:
System ID: NCT05082519