ITCC-101/APAL2020D - A randomized phase 3 trial of fludarabine/cytarabine/gemtuzumab ozogamicin with or without venetoclax in children with relapsed AML (A subtrial of the PedAL/EuPAL relapsed acute leukemia master protocol)

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: Not specified
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- participants must be at least 29 days of age and less than 21 years of age at enrollment - participants must have enrolled on APAL2020SC, NCT Number: NCT04726241 - children, adolescents, and young adults with acute myeloid leukemia without FLT3/internal tandem duplication (ITD) mutation - second relapse who are sufficiently fit to undergo another round of intensive chemotherapy - first relapse who per investigator discretion cannot tolerate additional anthracycline containing chemotherapy - see link to clinicaltrials.gov for complete criteria

Exclusion Criteria:

- participants with Down syndrome - participants with Acute promyelocytic leukemia (APL) or Juvenile myelomonocytic leukemia (JMML) - study staff will review additional exclusion criteria

Conditions & Interventions

Interventions:
Drug: Azacitidine, Drug: Cytarabine, Drug: Fludarabine, Drug: Gemtuzumab Ozogamicin, Drug: Venetoclax
Conditions:
Cancer, Cancer
Keywords:
Acute Myeloid Leukemia, AML

More Information

Description: A study to evaluate if the randomized addition of venetoclax to a chemotherapy backbone (fludarabine/cytarabine/gemtuzumab ozogamicin [GO]) improves survival of children/adolescents/young adults with acute myeloid leukemia (AML) in 1st relapse who are unable to receive additional anthracyclines, or in 2nd relapse.
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