MT2020-35 - COG AAML1831 - A Phase 3 Randomized Trial for Patients With De Novo AML Comparing Standard Therapy Including Gemtuzumab Ozogamicin (GO) to CPX-351 With GO, and the Addition of the FLT3 Inhibitor Gilteritinib for Patients With FLT3 Mutations

Status: Recruiting

Eligibility Criteria

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

Inclusion Criteria:

- patients must be less than 22 years of age at the time of study enrollment - all patients must be enrolled on APEC14B1 and consented to Eligibility Screening (Part A) prior to enrollment and treatment on AAML1831 - patient must be newly diagnosed with de novo Acute Myeloid Leukemia (AML) - see link to clinicaltrials.gov for additional inclusion criteria

Exclusion Criteria:

- any concurrent malignancy - female patients who are pregnant - lactating females who plan to breastfeed their infants - see link to clinicaltrials.com for additional exclusion criteria

Conditions & Interventions

Interventions:
Procedure: Allogeneic Hematopoietic Stem Cell Transplantation, Drug: Asparaginase Erwinia chrysanthemi, Procedure: Biospecimen Collection, Procedure: Bone Marrow Aspiration, Procedure: Bone Marrow Biopsy, Procedure: Computed Tomography, Drug: Cytarabine, Drug: Daunorubicin Hydrochloride, Drug: Dexrazoxane Hydrochloride, Drug: Etoposide, Other: Fludeoxyglucose F-18, Drug: Gemtuzumab Ozogamicin, Drug: Gilteritinib Fumarate, Drug: Liposome-encapsulated Daunorubicin-Cytarabine, Procedure: Magnetic Resonance Imaging, Drug: Methotrexate, Drug: Mitoxantrone Hydrochloride, Procedure: Positron Emission Tomography, Other: Questionnaire Administration, Drug: Therapeutic Hydrocortisone
Conditions:
Cancer
Keywords:
Acute Myeloid Leukemia, AML

More Information

Description: The overall goal of this study is to compare the effects, good and/or bad, of CPX-351 with daunorubicin and cytarabine on people with newly diagnosed AML to find out which is better, and to find out what effects, good and/or bad, the drug gilteritinib has when given with chemotherapy to children and young adults with newly diagnosed AML and the FLT3/ITD mutation or non-ITD FLT3 activating mutations.
Study Contact: Allison Fullenkamp - fulle631@umn.edu
Principal Investigator: Peter Gordon
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