

## 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](https://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](https://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](mailto:fulle631@umn.edu)

**Principal Investigator:** Peter Gordon

**Phase:** PHASE3

**IRB Number:** SITE00000965

---

Thank you for choosing StudyFinder. Please visit <http://studyfinder.umn.edu> to find a Study which is right for you and contact [sfinder@umn.edu](mailto:sfinder@umn.edu) if you have questions or need assistance.