# Clinical Trials Data KIT - Document 69

# Daunorubicin Hydrochloride, Cytarabine, and Nilotinib in Treating Patients With Newly Diagnosed Acute Myeloid Leukemia

## Clinical Trial: https://clinicaltrials.gov/study/NCT01806571

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Untreated, histological confirmed acute myeloid leukemia (AML) based on World Health Organization (WHO) 2008 criteria with Kit expression (cluster of differentiation \\[CD\\] 117) of myeloblasts \\>= 20% by flow cytometry from bone marrow aspirate at diagnosis\n\* Eastern Cooperative Oncology Group (ECOG) performance status (PS) 0, 1, or 2\n\* Magnesium within normal limits (WNL)\n\* Potassium WNL\n\* Phosphorus WNL\n\* Serum amylase =\\< 1.5 x upper limit of normal (ULN)\n\* Serum lipase =\\< 1.5 x ULN\n\* Total bilirubin =\\< 1.5 x ULN (does not apply to patients with isolated hyperbilirubinemia \\[e.g., Gilbert's disease\\], in that case direct bilirubin should be =\\< 2 x ULN)\n\* Alkaline phosphatase =\\< 3 x ULN\n\* Serum glutamic-oxaloacetic transaminase (SGOT) (aspartate aminotransferase \\[AST\\]) =\\< 3 x ULN\n\* Creatinine =\\<1.5 x ULN\n\* Negative pregnancy test done =\\< 7 days prior to registration, for women of childbearing potential only\n\* Provide informed written consent\n\* Willing to return to consenting Mayo Clinic (Mayo Clinic's campus in Rochester, Mayo Clinic's campus in Arizona, or Mayo Clinic's campus in Florida) institution for follow-up during the active monitoring phase of the study\n\* Willing to provide bone marrow aspirate and blood samples for correlative research purposes\n\nExclusion Criteria:\n\n\* Any of the following because this study involves investigational agent(s) whose genotoxic, mutagenic and teratogenic effects on the developing fetus and newborn are unknown\n\n \* Pregnant women\n \* Nursing women\n \* Men or women of childbearing potential who are unwilling to employ adequate contraception throughout the study and for 3 months after completion of study treatment\n\* Co-morbid systemic illnesses or other severe concurrent disease which, in the judgment of the investigator, would make the patient inappropriate for entry into this study or interfere significantly with the proper assessment of safety and toxicity of the prescribed regimens\n\* Immunocompromised patients (other than that related to the use of corticosteroids) including patients known to be human immunodeficiency virus (HIV) positive\n\* Uncontrolled intercurrent illness including, but not limited to, ongoing or active infection, or psychiatric illness/social situations that would limit compliance with study requirements\n\* Receiving any other investigational agent which would be considered as a treatment for the primary neoplasm\n\* Other active malignancy =\\< 3 years prior to registration; EXCEPTIONS: non-melanotic skin cancer or carcinoma-in-situ of the cervix\n\* Previous treatment with chemotherapy or any other tyrosine kinase inhibitor for a hematological disorder; Exceptions: patients with prior diagnosis of myelodysplastic syndrome (MDS) and/or treatment with hypomethylating agent (azacytidine or decitabine) are not excluded, prior hydroxyurea allowed\n\* Impaired cardiac function including any one of the following:\n\n \* Inability to monitor the QT interval on electrocardiogram (ECG)\n \* Congenital long QT syndrome or a known family history of long QT syndrome\n \* Clinically significant resting brachycardia (\\< 50 beats per minute)\n \* Corrected QT (QTc) \\> 450 msec on baseline ECG; if QTc \\> 450 msec and electrolytes are not within normal ranges, electrolytes should be corrected and then the patient re-screened for QTc\n \* Myocardial infarction =\\< 12 months prior to starting study\n \* Other clinically significant uncontrolled heart disease (e.g. unstable angina, congestive heart failure or uncontrolled hypertension)\n \* History of or presence of clinically significant ventricular, atrial tachyarrhythmias or ejection fraction cutoff\n \* Left ventricle ejection fraction \\< 45%\n \* History of, congestive heart failure requiring use of ongoing maintenance therapy for life-threatening ventricular arrhythmias\n\* Patients currently receiving treatment with strong cytochrome P450 family 3, subfamily A, polypeptide 4 (CYP3A4) inhibitors and treatment that cannot be either discontinued or switched to a different medication prior to starting study drug; patients receiving any medications or substances that are strong or moderate inhibitors of CYP3A4\n\n \* Use of the following strong or moderate inhibitors is prohibited \\< 7 days prior to registration\n\n \* Strong inhibitors of CYP3A4/5 \\> 5-fold increase in the plasma area under the curve (AUC) values or more than 80% decrease in clearance\n\n \* Boceprevir (Victrelis)\n \* Clarithromycin (Biaxin, Biaxin XL)\n \* Conivaptan (Vaprisol)\n \* Grapefruit juice\n \* Indinavir (Crixivan)\n \* Itraconazole (Sporanox)\n \* Ketoconazole (Nizoral)\n \* Lopinavir/ritonavir (Kaletra)\n \* Mibefradil\n \* Nefazodone (Serzone)\n \* Nelfinavir (Viracept)\n \* Posaconazole (Noxafil)\n \* Ritonavir (Novir, Kaletra)\n \* Saquinivir (Fortovase, Invirase)\n \* Telaprevir (Incivek)\n \* Telithromycin (Ketek)\n \* Voriconazole (Vfend)\n \* Moderate inhibitors of CYP3A4/5 \\> 2-fold in the plasma AUC values or 50-80% decrease in clearance\n\n \* Amprenavir (Agenerase)\n \* Aprepitant (Emend)\n \* Atazanavir (Reyataz)\n \* Ciprofloxacin (Cipro)\n \* Darunavir (Prezista)\n \* Diltiazem (Cardizem, Cardizem CD, Cardizem LA, Cardizem SR, Cartia XT, Dilacor XR, Diltia XT, Taztia XT, Tiazac)\n \* Erythromycin (Erythrocin, E.E.S. , Ery-Tab, Eryc, EryPed, PCE)\n \* Fluconazole (Diflucan)\n \* Fosamprenavir (Lexiva)\n \* Imatinib (Gleevec)\n \* Verapamil (Calan, Calan SR, Covera-HS, Isoptin SR, Verelan, Verelan PM)\n\* Receiving any medications or substances that are inducers of CYP3A4; use of the following inducers are prohibited =\\< 7 days prior to registration\n\n \* Strong inducers of CYP3A4/5 \\> 80% decrease in AUC\n\n \* Avasimibe\n \* Carbamazepine (Carbatrol, Epitol, Equetro, Tegretol, Tegretol-XR)\n \* Phenytoin (Dilantin, Phenytek)\n \* Rifampin (Rifadin)\n \* St. John's wort\n \* Moderate inducers of CYP3A4/5 50-80% decrease in AUC\n\n \* Bosentan (Tracleer)\n \* Efavirenz (Sustiva)\n \* Etravirine (Intelence)\n \* Modafinil (Provigil)\n \* Nafcillin\n \* Nevirapine (Viramune)\n \* Phenobarbital (Luminal)\n \* Rifabutin (Mycobutin)\n \* Troglitazone\n\* Patients currently receiving treatment with any medications that have the potential to prolong the QT interval and the treatment cannot be either discontinued or switched to a different medication prior to starting study drug\n\* Impaired gastrointestinal (GI) function or GI disease that may significantly alter the absorption of study drug (e.g., ulcerative diseases, uncontrolled nausea, vomiting, diarrhea, malabsorption syndrome, small bowel resection or gastric bypass surgery)\n\* Acute or chronic pancreatic disease\n\* Known cytopathologically confirmed central nervous system (CNS) infiltration\n\* Acute or chronic liver disease or severe renal disease considered unrelated to the cancer\n\* History of significant congenital or acquired bleeding disorder unrelated to cancer\n\* Major surgery =\\< 4 weeks prior to registration of the study or who have not recovered from prior surgery\n\* Treatment with other investigational agents =\\< 14 days of registration\n\* Diagnosis of AML-M3 (or acute promyelocytic leukemia)",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
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"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
]

Question:  
Based on the following clinical trial information, would a patient with a KIT gene mutation be eligible for the clinical trial?

Answer:  
This trial requires patients to have AML with Kit \*expression\* of myeloblasts ≥ 20%. A KIT gene \*mutation\* is not explicitly mentioned as an inclusion or exclusion criterion. Therefore, having a KIT mutation does \*not\* automatically qualify or disqualify a patient. The key factor is the level of Kit expression (CD117) on the myeloblasts.  
  
A patient with a KIT mutation \*could\* be eligible if their myeloblasts also exhibit Kit expression ≥ 20%. Further testing would be needed to determine the level of Kit expression.