# Testing the Use of Steroids and Tyrosine Kinase Inhibitors With Blinatumomab or Chemotherapy for Newly Diagnosed BCR-ABL-Positive Acute Lymphoblastic Leukemia in Adults

**Status:** RECRUITING

## Eligibility Criteria

**Age:** 18 years to 75 years old

This study is NOT accepting healthy

**Healthy Volunteers:** volunteers

**Inclusion Criteria:**

* ELIGIBILITY CRITERIA FOR PRE-REGISTRATION (TO STEP 0) * Patient must be \>= 18 and =\< 75 years of age * Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status between 0-3 * Patient must be newly diagnosed with B acute lymphoblastic leukemia (B-ALL) or is suspected to have acute lymphoblastic leukemia (ALL) * Patient must have BCR-ABL1 positive disease. The diagnosis of ALL and the presence of BCR-ABL translocation must be confirmed centrally. Patients can be registered and begin step 1 therapy while awaiting central laboratory eligibility confirmation * NOTE: Bone marrow aspirate and/or peripheral blood specimen must be submitted to the ECOG-American College of Radiology Imaging Network (ACRIN) Leukemia Laboratory at MD Anderson Cancer Center to determine patient's eligibility for registration to Step 1 or confirm patient evaluability. Centrally fluorescence-activated cell sorting (FACS) analysis will be performed to determine B-ALL and to exclude acute myeloid leukemia (AML) or acute bi-phenotypic leukemia and baseline BCR-ABL status will be determined by fluorescent in situ hybridization (FISH). The ECOG-ACRIN Leukemia Laboratory will forward results within 48 hours of receipt of the specimen to the submitting institution. Bone marrow aspirate is to be from first pull (initial or re-direct). Specimens must contain sufficient blast cells. In cases where the bone marrow aspiration may be inadequate, or the bone marrow examination has already been performed prior to study consent and enrollment on Step 0, peripheral blood may be submitted, with recommendation that adequate circulating blasts are present (\> 10%). If a diagnosis of BCR-ABL positive B-ALL has already been established by local Clinical Laboratory Improvement Act (CLIA) certified laboratories, the patient may be registered to step 1 without waiting for central confirmation * Patient must not have a diagnosis of BCR/ABL T-ALL * Patient must not have received chemotherapy for B-ALL. Patients who received up to five days of therapy (hydroxyurea and/or steroids of any kind) with the aim to reduce disease burden prior to study registration to Step 1 are eligible * Patient must not have unstable epilepsy that requires treatment * Patients with lymphoid blast crisis chronic myeloid leukemia (CML) are not eligible * ELIGIBILITY CRITERIA FOR REGISTRATION TO STEP 1 * Patient must have a diagnosis of Philadelphia chromosome positive (Ph+) ALL that has been determined locally and bone marrow and/or peripheral blood was sent and receipt confirmed for central confirmation or determined centrally by the ECOG-ACRIN Leukemia Laboratory at MD Anderson Cancer Center * Patient must not be pregnant or breast-feeding due to the potential harm to an unborn fetus and possible risk for adverse events in nursing infants with the treatment regimens being used. All patients of childbearing potential must have a blood test or urine study within 14 days prior to registration to rule out pregnancy. A patient of childbearing potential is defined as any woman, regardless of sexual orientation or whether they have undergone tubal ligation, who meets the following criteria: 1) has achieved menarche at some point, 2) has not undergone a hysterectomy or bilateral oophorectomy, or 3) has not been naturally postmenopausal (amenorrhea following cancer therapy does not rule out childbearing potential) for at least 24 consecutive months (i.e., has had menses at any time in the preceding 24 consecutive months) * Patients must not expect to conceive or father children by using accepted and effective method(s) of contraception or by abstaining from sexual intercourse from the time of step 1 registration, while on study treatment, and until at least six months after the last dose of study treatment * Total bilirubin =\< 3 mg/dL (patients with Gilbert's syndrome must have a total bilirubin =\< 5 mg/dL) (obtained =\< 28 days prior to step 1 registration) * Aspartate aminotransferase (AST) (serum glutamic-oxaloacetic transaminase \[SGOT\]) and alanine aminotransferase (ALT) (serum glutamate pyruvate transaminase \[SGPT\]) =\< 2.5 X the institutional upper limit of normal (ULN) (obtained =\< 28 days prior to step 1 registration) * Estimated creatinine clearance \> 45 mL/min (based on Cockcroft-Gault equation) (obtained =\< 28 days prior to step 1 registration) * Patients with acute organ dysfunction at step 1 registration, which may be attributed to leukemia can be registered regardless of lab results at presentation. Such patients will be allowed to register and can start Arm A steroid + TKI therapy but will only be allowed to proceed to step 2 randomization if the eligibility criteria outlined is met * Patients who presented with no evidence of acute organ dysfunction but during step 0 experienced a rise in liver enzymes which investigator suspects to be a side effect of any of prescribed drugs, are allowed to be registered regardless of the level of liver enzymes. Step 2 randomization must be withheld until the eligibility criteria outline is met but no more than 14 days after concluding Arm A therapy * Human immunodeficiency virus (HIV)-infected patients on effective anti-retroviral therapy with undetectable viral load within 6 months are eligible for this trial * For patients with evidence of chronic hepatitis B virus (HBV) infection, the HBV viral load must be undetectable or on suppressive therapy, if indicated * Patients with a history of hepatitis C virus (HCV) infection must have an undetectable HCV viral load and if indicated, on treatment * Patients with a prior malignancy whose natural history or treatment does not have the potential to interfere with the safety or efficacy assessment of the investigational regimen are eligible for this trial * Patient must not have active concomitant malignancy. Patients on chronic hormonal therapy for breast or prostate cancer or patients treated with maintenance with targeted agents but are in remission with no evidence for the primary malignancies are eligible * Patient must not have complaints of symptoms and/or have clinical and/or radiological signs that indicate an uncontrolled infection or any other concurrent medical condition that could be exacerbated by the treatment or would seriously complicate compliance with the protocol * Patients with known history or current symptoms of cardiac disease, or history of treatment with cardiotoxic agents, should have a clinical risk assessment of cardiac function using the New York Heart Association Functional Classification. To be eligible for this trial, patients must be class 2B or better * Investigators must confirm which TKI patient is to receive * NOTE: Patients with known T315I mutation status should receive ponatinib treatment * NOTE: In situations due to insurance coverage issues and the pre-selected TKI is not immediately available, patients can receive dasatinib or imatinib during step 1. The investigator must re-specify dasatinib or ponatinib prior to step 2 randomization and from then on patients must receive the pre-selected TKI only * ELIGIBILITY CRITERIA FOR RANDOMIZATION TO STEP 2 * Patient must have completed at least 7 and no more than 21 days of protocol-treatment on Arm A prior to step 2 randomization. (Days in which arm A therapy was withheld for any reason are not counted) * NOTE: First day of steroids prescription after registration will be considered as the first day of study therapy. The selected TKI must be initiated prior to randomization * Patients who presented with acute organ dysfunction within 2 weeks of registration to step 1 must have total bilirubin =\< 2 X institutional upper limit of normal (ULN) * AST(SGOT) and ALT(SGPT) =\< 2 X the institutional upper limit of normal (ULN) * Estimated creatinine clearance \> 45 mL/min (based on Cockcroft-Gault equation) * Investigators must confirm which TKI patient is to receive. * NOTE: Patients with known T315I mutation status should receive ponatinib treatment * For patients under age 70, intended chemotherapy regimen must have been determined prior to randomization * Patient must not have active central nervous system (CNS) involvement by leukemic blasts. Patients with signs of CNS involvement at presentation are eligible for randomization if clearance of blasts from the cerebrospinal fluid (CSF) is demonstrated * Patients must have resolved any serious infectious complications related to therapy * Any significant medical complications related to therapy must have resolved * ELIGIBILITY CRITERIA FOR REGISTRATION TO STEP 3 (RE-INDUCTION) * Institution has received centralized MRD results confirming positive status * Patients who presented with acute organ dysfunction within 2 weeks of registration to step 1 must have total bilirubin =\< 2 X institutional ULN * Patients who presented with acute organ dysfunction must have AST (SGOT)/ALT (SGPT) =\< 2 X institutional upper limit of normal (ULN) * Patients who presented with acute organ dysfunction must have an estimated creatinine clearance \> 45 mL/min (based on Cockcroft-Gault equation) * Investigators must confirm which TKI patient is to receive * NOTE: Patients with known T315I mutation status should receive ponatinib treatment * For patients under age 70 and previously assigned to Arm C, intended chemotherapy regimen must have been determined * Step 3 (Re-Induction): Patients must have resolved any serious infectious complications related to therapy * Step 3 (Re-Induction): Any significant medical complications related to therapy must have resolved

## Conditions & Interventions

**Interventions:**

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PROCEDURE: Biospecimen Collection, BIOLOGICAL: Blinatumomab, PROCEDURE: Bone Marrow Aspiration and Biopsy, DRUG: Cyclophosphamide, DRUG: Cytarabine, DRUG: Dasatinib, DRUG: Dexamethasone, DRUG: Doxorubicin Hydrochloride, PROCEDURE: Echocardiography Test, PROCEDURE: Electrocardiography, PROCEDURE: Lumbar Puncture, DRUG: Mesna, DRUG: Methotrexate, PROCEDURE: Multigated Acquisition Scan, DRUG: Ponatinib Hydrochloride, DRUG: Prednisone, DRUG: Vincristine Sulfate
**Conditions:**
B Acute Lymphoblastic Leukemia With t(9,22)(q34.1,q11.2), BCR-ABL1

## More Information

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**Phase:** PHASE3
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