

A Phase 3, Multicenter, Randomized, Double-Blind Study of the Efficacy and Safety of Rezafungin for Injection Versus the Standard Antimicrobial Regimen to Prevent Invasive Fungal Diseases in Adults Undergoing Allogeneic Blood and Marrow Transplantation (The ReSPECT Study)

Status: Recruiting

Eligibility Criteria

Sex: Male or Female

Age Group: 18 years and over

This study is NOT accepting healthy volunteers

Inclusion Criteria:

- receiving a human leukocyte antigen (HLA) matched or unmatched peripheral bone marrow transplant (BMT) - diagnosis of one of the following underlying diseases: acute myeloid leukemia (AML), acute lymphoblastic leukemia, acute undifferentiated leukemia, acute biphenotypic leukemia, or chronic myelogenous leukemia - women and men must agree to use birth control for 120 days after last dose of study drug - see link to clinicaltrials.gov for completed inclusion and exclusion criteria

Exclusion Criteria:

- diagnosis of AML not in remission - significant heart or lung disease - previous allogeneic BMT - ataxia, neuropathy or tremors; or a diagnosis of multiple sclerosis or a movement disorder (including Parkinson's disease or Huntington's disease)

Conditions & Interventions

Conditions:

Infectious Diseases

Keywords:

BMT, Bone Marrow Transplant, Candidemia, Fungal Infection, Infection, Infectious Disease, Mycoses

More Information

Description: One type of infection that is possible after bone marrow transplant is called an invasive fungal disease (IFD), a type of fungal infection that has the ability to spread throughout the body. In this study, rezafungin will be compared with the currently approved drugs for the prevention of IFD. The currently approved drugs are referred to as the standard antimicrobial regimen (SAR) which is posaconazole or fluconazole. We want to learn if rezafungin is safe and tolerable, if it is effective in preventing IFD compared to the standard treatment and to find out how much rezafungin is in blood over time after study drug has been given.

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Phase: PHASE3

IRB

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