A Phase III, adjudicator-blinded, randomised study to evaluate the efficacy and safety of treatment with olorofim versus treatment with AmBisome® followed by standard of care (SOC) in patients with invasive fungal disease (IFD) caused by Aspergillus species

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: 18 years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- over 18 years old - weigh more than 40 kg (88 pounds) - Invasive Aspergillosis (IA) at any site - require therapy with an antifungal agent other than a mold-active azole

Exclusion Criteria:

- women who are pregnant or breastfeeding - known history of allergy, hypersensitivity, or any serious reaction to any component of the study drug - people with chronic aspergillosis, aspergilloma, or allergic bronchopulmonary aspergillosis - human immunodeficiency virus (HIV) infection but not currently receiving antiretroviral therapy - certain heart and liver conditions (study staff will review)

Conditions & Interventions

Interventions:
Drug: AmBisome®, Drug: Olorofim
Conditions:
Infectious Diseases, Respiratory System
Keywords:
Aspergillosis, IA, Invasive Aspergillosis (IA), Lung Infection

More Information

Description: This study will look at an investigational study drug, called olorofim, to determine how safe the study drug is, how well it is tolerated and whether it is effective compared to AmBisome® (a standard of care treatment) to treat invasive fungal disease (IFD). We expect that you will be in this research study for up to 18 weeks or just over 4 months.
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