

Title: UARK 2008-11, A Prospective, Randomized Trial comparing the Efficacy of Anidulafungin and Voriconazole in combination to that of Voriconazole alone when used for Primary Therapy of Proven or probable Invasive Aspergillosis

Sponsor: Pfizer

PI: Elias Anaissie, M.D.

Phase: IV

Purpose: The usual treatment for patients who have infections caused by a fungus is treatment with an antifungal medicine. The reason for carrying out this research is to find out how taking a combination of antifungal medicines (voriconazole and anidulafungin) to treat invasive Aspergillus infections compares to taking treatment with a single medicine, voriconazole.

Eligibility: This study will include patients who have either received a stem cell transplant and/or who have developed cancer of the blood or bone marrow.

To be included in the study, your doctor must have a high suspicion that you have invasive infection with Aspergillus. The diagnosis can be pending at the time that you enter the study. Your doctor will perform testing during the study to confirm whether you have or do not have infection with Aspergillus.

Treatment: There are two possible treatment groups in this study. Placebo in this study is a liquid that does not contain any drug. Anidulafungin contains some alcohol. On Day 1, the dose of anidulafungin that you will receive will contain 12 grams of alcohol. This is less than the amount of alcohol in one drink, and the dose will be given to you over a period of 3 hours. After Day 1, the doses of anidulafungin that you receive will contain 6 grams of alcohol per dose, and each dose will be given to you over a period of one and a half hours. If, for some reason, you are unable or unwilling to take a drug that contains this small amount of alcohol, or if you have questions about the amount of alcohol in the drug, you should discuss these concerns with your doctor.

Contact: Nathan Petty pettynathanm@uams.edu (501) 526-6990 ext. 2435