ongoing trials - trial from www.clinicaltrials.gov

Efficacy Study of AeroVanc for the Treatment of Persistent MRSA Lung Infection in Cystic Fibrosis Patients - Phase 2 - Completed

Code: NCT01746095 **Year:** 2012 **Date:** March 2013 **Author:** Savara Inc.

Study design (if review, criteria of inclusion for studies)

Completed. No study results posted - Allocation: Randomized|Endpoint Classification: Safety/Efficacy Study|Intervention Model: Parallel Assignment|Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)|Primary Purpose: Treatment

Participants

Child|Adult|Senior

Interventions

Drug: Vancomycin inhalation powder|Drug: Placebo inhalation powder

Outcome measures

Change from Baseline at Day 29 of the dosing period (start of AeroVanc/Placebo administration is considered Day 1 of the dosing period) in the number of MRSA colony forming units (CFU) in sputum culture.|Change from Baseline in each pulmonary function test (PFT)|Change from Baseline in Cystic Fibrosis Respiratory Symptom Diary (CF-RSD) scores.|Change from Baseline in MRSA sputum density.|Time from start of dosing to first administration of other antimicrobial medications (oral, intravenous and/or inhaled) due to respiratory symptoms.|Time from start of dosing to exacerbation of signs/symptoms (Fuchs criteria).|Change from Baseline in high sensitivity CRP and blood neutrophils

http://ClinicalTrials.gov/show/NCT01746095

Keywords

Vancomycin; other anti-bacterial agents; Anti-Bacterial Agents; pharmacological_intervention; Inhalation OR nebulised; Powders; Staphylococcus aureus; Respiratory Tract Infections; Respiratory Tract Diseases; Infection; Bacterial Infections;