ongoing trials - trial from www.clinicaltrials.gov

Study to Assess Amphotericin B Cystetic for Inhalation (ABCI) Doses in Healthy Volunteers & People With Cystic Fibrosis - Phase 1|Phase 2 - Recruiting

Code: NCT05802264 **Year:** 2023 **Date:** March 21, 2023

Author: Cystetic Medicines, Inc.|DevPro Biopharma

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

Interventional - Allocation: Randomized|Intervention Model: Parallel Assignment|Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)|Primary Purpose: Treatment

Participants

Cystic Fibrosis - 16 Years and older (Child, Adult, Older Adult)

Interventions

Combination Product: ABCI|Combination Product: Placebo

Outcome measures

Adverse Events (AEs), and Serious Adverse Events (SAEs)|Pharmacokinetics (PK) Profile - SAD Cmax|Pharmacokinetics (PK) Profile - SAD Tmax|Pharmacokinetics (PK) Profile - SAD AUC0-24|Pharmacokinetics (PK) Profile - SAD AUClast|Pharmacokinetics (PK) Profile - SAD AUCinf|Pharmacokinetics (PK) Profile - MAD Cmax|Pharmacokinetics (PK) Profile - MAD Tmax|Pharmacokinetics (PK) Profile - MAD AUC0-24|Pharmacokinetics (PK) Profile - SAD AUCtau|Pharmacokinetics (PK) Profile - MAD Plasma AmB trough assessments|Pharmacokinetics (PK) Profile - MAD AmB concentrations in BAL fluid|Pharmacokinetics (PK) Profile - Subjects with CF Cmax|Pharmacokinetics (PK) Profile - Subjects with CF Tmax|Pharmacokinetics (PK) Profile - Subjects with CF AUC0-24|Pharmacokinetics (PK) Profile - Subjects with CF AUCtau|Pharmacokinetics (PK) Profile - Subjects with CF trough AmB concentrations|Pharmacokinetics (PK) Profile - Subjects with CF Plasma AmB trough assessments|FEV1 - Subjects with CF|Questionnaire - Subjects with CF|FVC - Subjects with CF|Body weight - Subjects with CF

https://ClinicalTrials.gov/show/NCT05802264

Keywords

Antifungal Agents; pharmacological_intervention; Allergic Bronchopulmonary Aspergillosis -ABPA-; Aspergillus; Fungi; Infection; Respiratory Tract Infections; Respiratory Tract Diseases; Amphotericin; Inhalation OR nebulised;