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A Phase 3 Open-label Study Evaluating the Longterm Safety and Efficacy of Elexacaftor/Tezacaftor/Ivacaftor in Cystic Fibrosis Subjects With Non-F508del CFTR Genotypes

Code:
EUCTR2021-005914-33

Year: 2021 **Date:** April 22, 2021

Author:

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

Interventional - Allocation: Randomized|Intervention Model: Parallel Assignment|Masking: None (Open Label)|Primary Purpose: Treatment

Participants

Cystic Fibrosis|Aspergillosis - 8 Years to 17 Years (Child)

Interventions

Drug: Posaconazole 100 MG [Noxafil]|Drug: Posaconazole 40 MG/ML

Outcome measures

Pharmacokinetic parameters of posaconazole|Aspergillus isolation from sputum cultures|Patients with a favourable clinical response and no signs of Aspergillus infection|Patients with no signs of Aspergillus infection|The proportion of participants experiencing AEs and SAEs

<https://www.clinicaltrialsregister.eu/ctr-search/trial/2021-005914-33/DE/>

Keywords

Adolescent; Adult; Antifungal Agents; Child; pharmacological_intervention; Allergic Bronchopulmonary Aspergillosis -ABPA-; Aspergillus; Fungi; Infection; Respiratory Tract Infections; Respiratory Tract Diseases; posaconazole;