ongoing trials - trial from other registries

A Phase 3 Study Evaluating the Pharmacokinetics, Safety, and Tolerability of VX 121/Tezacaftor/Deutivacaftor Triple Combination Therapy in Cystic Fibrosis Subjects 1 Through 11 Years of Age (VX21-121-105)

Code: CTIS-2024-513754-29-00 **Year:** 2024 **Date:** new **Author:**

Participants

15 patients 0-17 years with Cystic Fibrosis

Interventions

VX-121/VX-661/VX-561 Film-coated tablet, Kalydeco 75 mg film-coated tablets, VX-445/VX-661/VX-770 film-coated fixed-dose combination tablet, VX-121/VX-661/VX-561 Film-coated tablet, Kaftrio 37.5 mg/25 mg/50 mg film-coated tablets, Kalydeco 150 mg film-coated tablets, VX-445/VX-661/VX-770 fixed-dose combination tablet

Outcome measures

Part A: PK parameters of VX-121, TEZ, D-IVA, and relevant metabolites, Part A: Safety and tolerability as determined by adverse events (AEs), clinical laboratory values, standard 12 lead ECGs, vital signs, and pulse oximetry, Part B: Safety and tolerability as determined by AEs, clinical laboratory values, standard 12-lead ECGs, vital signs, and pulse oximetry

Keywords

CFTR Modulators; Genetic Predisposition to Disease; pharmacological_intervention; placebo; VX-770; VX-121; ivacaftor; Aminophenols; tezacaftor; VX-661; vanzacaftor; deutivacaftor; elexacaftor; VX-445; VX-561;